UNITED STATES DISTRICT COURT
FOR THE MASSACHUSETTS

UNITED STATES OF AMERICA	)	
	)	**Criminal No. 23-cr-________**
v.	)	24cr10144
	)	
MAGELLAN DIAGNOSTICS, INC.	)	
	)	
Defendant.	)	
	)	
	)	

DEFERRED PROSECUTION AGREEMENT

The United States Attorney's Office, by its attorney, Joshua S. Levy, Acting United States Attorney for the District of Massachusetts (the "Office") and defendant Magellan Diagnostics, Inc. ("Magellan" or "the Company") hereby enter into this Deferred Prosecution Agreement (the "Agreement"). The terms and conditions of this Agreement are as follows:

Criminal Information and Acceptance of Responsibility

1. The Company acknowledges and agrees that the Office will file the attached criminal Information in the United States District Court for the District of Massachusetts charging the Company with (1) conspiracy to commit wire fraud in violation of Title 18, United States Code, Section 1349; and (2) conspiracy to defraud the United States in violation of Title 18, United States Code, Section 371 (hereinafter, "the Felony Information"). In so doing, the Company: (a) knowingly waives any right it may have to indictment on these charges, as well as all rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); (b) agrees to venue of the case in the District of Massachusetts and knowingly waives any objection with respect to venue to any charges by the United States arising out of the conduct described in the Statement of Facts attached hereto as Attachment A ("Statement of Facts"); (c) knowingly waives any applicable

statute of limitations and any legal or procedural defects in the Felony Information; and (d) consents to the filing of the Felony Information, as provided under the terms of this Agreement, in the United States District Court for the District of Massachusetts. The Office agrees to defer prosecution of the Company pursuant to the terms and conditions described below.

2. The Company admits, accepts, and acknowledges that it is responsible under United States law for the acts of its officers, directors, employees, and agents as charged in the Felony Information, and as set forth in the Statement of Facts, and that the allegations described in the Felony Information and the facts described in the Statement of Facts are true and accurate. The Company agrees that, as of the Effective Date (as defined herein), in any prosecution that is referenced by this Agreement, it will not dispute the Statement of Facts set forth in this Agreement, and, in any such prosecution, the Statement of Facts shall be admissible as: (a) substantive evidence offered by the government in its case-in-chief and rebuttal case; (b) impeachment evidence offered by the government on cross-examination; and (c) evidence at any sentencing hearing or other hearing. In addition, in connection therewith, the Company agrees not to assert any claim under the United States Constitution, Rule 410 of the Federal Rules of Evidence, Rule 11(f) of the Federal Rules of Criminal Procedure, Section 1B1.1(a) of the United States Sentencing Guidelines, or any other federal rule that the Statement of Facts should be suppressed or is otherwise inadmissible as evidence in any form.

Term of the Agreement

3. This Agreement is effective for a period beginning on the date on which the Information is filed (the "Effective Date") and ending twenty-four (24) months from the later of the Effective Date or the date on which the independent compliance monitor (the "Monitor") is retained by the Company, as described in Paragraphs 14–17 below (the "Term"). The Company

agrees, however, that, in the event the Office determines, in its sole discretion, that the Company has knowingly violated any provision of this Agreement or has failed to completely perform or fulfill each of the Company's obligations under this Agreement, an extension or extensions of the Term may be imposed by the Office, in its sole discretion, for up to a total additional time period of one year, without prejudice to the Office's right to proceed as provided in Paragraphs 20–23 below. Any extension of the Agreement extends all terms of this Agreement, including the terms of the reporting requirements and monitorship in Attachment D, for an equivalent period. Conversely, in the event the Office finds, in its sole discretion, independently or after a request by the Company, that there exists a change in circumstances sufficient to eliminate the need for the reporting requirements and monitorship in Attachment D, and that the other provisions of this Agreement have been satisfied, the Agreement may be terminated early. If the Court refuses to grant exclusion of time under the Speedy Trial Act, Title 18, United States Code, Section 3161(h)(2), the Term shall be deemed to have not begun, and all provisions of this Agreement shall be deemed null and void, except: (a) the provisions contained within Paragraph 2 of this Agreement; and (b) the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts shall be tolled from the Effective Date of this Agreement until the date the Court refuses to grant the exclusion of time plus six months.

Relevant Considerations

4. The Office enters into this Agreement based on the individual facts and circumstances presented by this case and the Company, including:

a. The Company's acknowledgement of its conduct and acceptance of responsibility for that conduct;

b. The Company's cooperation in the investigation of this matter and the Company's commitment to continue cooperation with the government's investigation and prosecution of violations of federal law by individuals associated with Magellan;

c. The Company's commitment to enhanced compliance measures;

d. Remedial measures undertaken by the Company and its parent company and the Company's commitment to undertake additional remediation as identified herein;

e. The Company's guilty plea to two misdemeanor violations of the Food, Drug, and Cosmetic Act ("FDCA"), Title 21, United States Code, Sections 331 and 333 as charged in an information ("FDCA Information") filed by the Office in this matter, and payment of $32,700,000 in criminal fines and forfeiture in connection with the FDCA Information; and

f. The Company's commitment to fulfill all of the terms of this Agreement;

g. Accordingly, after considering (a) though (f) above, the Office believes that the appropriate resolution in this case is a deferred prosecution agreement with the Company, payment of victim compensation of at least $9,300,000 as detailed herein and in attachments to this Agreement; and the Company's agreement to report to the Office as set forth in the Compliance Reporting Requirements and to engage an independent compliance Monitor.

Future Cooperation and Disclosure Requirements

5. The Company shall cooperate fully with the Office in any and all matters relating to the facts and conduct described in this Agreement and the Statement of Facts until all investigations and prosecutions arising out of such conduct are concluded. At the request of the Office, the Company shall also cooperate fully with other domestic or foreign law enforcement and regulatory authorities and agencies in any investigation of the Company, its parent company or subsidiaries, or any of its present or former officers, directors, employees, agents, and

consultants, or any other party, in any and all matters relating to the facts and conduct described in this Agreement and the Statement of Facts. The Company's cooperation pursuant to this Paragraph is subject to applicable law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company must provide to the Office a description of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company bears the burden of establishing the validity of any such an assertion. The Company agrees that its cooperation pursuant to this paragraph shall include, but not be limited to, the following:

a. The Company shall truthfully disclose all factual information with respect to its activities, those of its parent company and subsidiaries, and those of its present and former directors, officers, employees, agents, and consultants, including any evidence or allegations and internal or external investigations, about which the Company has any knowledge or about which the Office may inquire. This obligation of truthful disclosure includes, but is not limited to, the obligation of the Company to provide to the Office, upon request, any non-privileged document, record, or other tangible evidence about which the Office may inquire of the Company.

b. Upon request of the Office, the Company shall designate knowledgeable employees, agents, or attorneys to provide to the Office the information and materials described in Paragraph 5(a) above on behalf of the Company. The Company agrees that it must at all times provide complete, truthful, and accurate information to the Office.

c. As requested by the Office, the Company shall make available for interviews or testimony any present officers, directors, employees, agents, and consultants of the Company, its parent company and subsidiaries. This obligation includes, but is not limited to, sworn testimony as well as interviews with domestic or foreign law enforcement and regulatory

authorities. Cooperation under this Paragraph shall include identification of witnesses who, to the knowledge of the Company, may have material information regarding the matters under investigation.

d. With respect to any information, testimony, documents, records, or other tangible evidence provided to the Office pursuant to this Agreement, the Company consents to any and all disclosures to other governmental authorities, including United States authorities and those of a foreign government, of such materials as the Office, in its sole discretion, shall deem appropriate.

Victim Compensation

6. The Company agrees to establish a Victim Compensation Fund of at least $9,300,000 to compensate patients and/or minor patients' legal guardians who were harmed by the conduct described in the Statement of Facts between June 27, 2013 and May 31, 2017. The Company shall establish a dedicated bank account for the Victim Compensation Fund and make deposits to the account according to the following schedule: $3,000,000 shall be deposited no later than 15 days after the Effective Date of this Agreement; $3,000,000 shall be deposited no later than one year after the Effective Date of this Agreement; and $3,300,000 shall be deposited no later than two years after the Effective Date of this Agreement.

7. The parties agree that the Monitor shall, according to the processes and standards described in Attachments D and F, (i) oversee the Company's efforts to identify and notify potential victims; (ii) review and evaluate victim compensation claims; (iii) oversee the Company's payment of victim compensation claims that the Monitor determines shall be paid; and (iv) resolve any disputes between a victim and the Company concerning the victim's entitlement to compensation. The Company agrees to fully compensate victims the Monitor determines to be

entitled to victim compensation, even if the total compensation requires the Company to add funds to the dedicated bank account.

8. The Company agrees to pay for all costs, fees, and expenses incurred in connection with the dedicated bank account, the Monitor's oversight and administration of the victim compensation process, and any victim outreach efforts.

9. The parties agree that any portion of the Victim Compensation Fund that (a) has not been paid out to victims at the conclusion of the Victim Payment Period (as that term is defined in Attachment F) and (b) is not subject to a pending claim submitted to the Monitor (as specified in Attachment F) shall instead be paid to qualified Childhood Lead Poisoning Prevention Programs ("CLPPPs"). CLPPPs are state and local programs dedicated to reducing childhood lead poisoning as a public health problem through strengthening blood testing, reporting, and surveillance, linking exposed children to recommended services, and targeted population-based interventions. The parties agree that the Monitor shall, according to the processes and standards described in Attachments D and F, determine—subject to approval by the Office—which CLPPPs are qualified to receive payments and the amount each CLPPP shall receive.

Conditional Release from Liability

10. Subject to Paragraphs 20–23, the Office agrees, except as provided in this Agreement and the Company's plea agreement concerning the FDCA Information, that it will not bring any criminal or civil case against the Company relating to any of the conduct described in the Statement of Facts, the Felony Information, or the FDCA Information filed pursuant to this Agreement. The Office, however, may use any information related to the conduct described in the Statement of Facts against the Company: (a) in a prosecution for perjury or obstruction of justice; (b) in a prosecution for making a false statement; (c) in a prosecution or other proceeding relating

to any crime of violence; or (d) in a prosecution or other proceeding relating to a violation of any provision of Title 26 of the United States Code.

a. This Agreement does not provide any protection against prosecution for any future conduct by the Company.

b. In addition, this Agreement does not provide any protection against prosecution of any individuals, regardless of their affiliation with the Company.

Corporate Compliance Program

11. The Company has implemented and will continue to implement a compliance and ethics program designed to prevent and detect violations of the FDCA and its associated regulations throughout its operations, including those of its subsidiaries, agents, and joint ventures, and those of its contractors and subcontractors whose responsibilities relate to the Company's interactions with domestic government agencies (including the Food and Drug Administration ("FDA")) and the Company's communications with customers about FDA-regulated products, including, but not limited to, the elements set forth in Attachment C.

12. In order to address any deficiencies in its internal controls, policies, and procedures, the Company represents that it has undertaken, and will continue to undertake in the future, in a manner consistent with all of its obligations under this Agreement, a review of its existing internal controls, policies, and procedures regarding compliance with the FDCA, focusing on the Company's interactions with domestic government agencies (including the FDA) and the Company's handling of complaints or malfunction reports concerning FDA-regulated products. Where necessary and appropriate, the Company agrees to adopt a new compliance program, or to modify its existing one, including internal controls, compliance policies, and procedures in order to ensure that it maintains an effective compliance program, including a system of internal

controls, designed to effectively detect and deter violations of the FDCA and its associated regulations. The compliance program, including the internal controls system, will include, but not be limited to, the elements set forth in Attachment C.

Corporate Compliance Reporting

13. The Company agrees that it will report to the Office during the Term regarding remediation and implementation of the compliance measures described in Attachment C. These reports will be prepared in accordance with, and at the frequency defined in, Attachment D.

Independent Compliance Monitor

14. Promptly after the Office's selection of a Monitor pursuant to Paragraph 16, the Company agrees to retain the Monitor for the term specified in Paragraph 17. The Monitor's duties and authority, and the obligations of the Company with respect to the Monitor and the Office, are set forth in Attachment D. Within 15 business days after the Effective Date of this Agreement, the Company shall submit a written proposal identifying three Monitor candidates, and, at a minimum, providing the following:

a. a description of each candidate's qualifications and credentials in support of the evaluative considerations and factors listed below;

b. a written certification by the Company that it will not employ or be affiliated with the Monitor for a period of not less than two years from the date of the termination of the monitorship;

c. a written certification by each of the candidates that the candidate is not a current or recent (i.e., within the prior two years) employee, agent, or representative of the Company and holds no interest in, and has no relationship with, the Company, its parent company, subsidiaries, or related entities, or its employees, officers, or directors;

d. a written certification by each of the candidates that the candidate has notified any clients that the candidate represents in a matter involving the Office (or any other Department of Justice component handling the Monitor selection process), and that the candidate has either obtained a waiver from those clients or has withdrawn as counsel in the other matter(s); and

e. A statement identifying the Monitor candidate that is the Company's first, second, and third choice to serve as the Monitor.

15. The Monitor candidates or their team members shall have, at a minimum, the following qualifications:

a. experience and expertise with respect to designing and/or reviewing corporate compliance policies, procedures, and internal controls, including those specific to maintaining compliance with the FDCA and its associated regulations and other applicable laws concerning in vitro diagnostic testing devices;

b. experience and expertise with mass tort litigation, product liability, and/or personal injury;

c. the ability to access and deploy resources as necessary to discharge the Monitor's duties as described in this Agreement; and

d. sufficient independence from the Company to ensure effective and impartial performance of the Monitor's duties as described in this Agreement.

16. The Office retains the right, in its sole discretion, to choose the Monitor from among the candidates proposed by the Company consistent with DOJ policy concerning the selection of corporate monitors. Any submission or selection of a Monitor candidate by either the Company or the Office shall be made without unlawful discrimination against any person or class

of persons. If the Office determines, in its sole discretion, that any or all of the three candidates lack the requisite qualifications, the Office shall notify the Company and request that the Company propose another candidate or candidates within 20 business days. This process shall continue until a Monitor acceptable to both parties is chosen. The Office and the Company will use their best efforts to complete the selection process within 60 calendar days of the Effective Date of this Agreement. The Office retains the right to determine that the Monitor should be removed if, in the Office's sole discretion, the Monitor fails to conduct the monitorship effectively, fails to comply with this Agreement, or no longer meets the qualifications outlined in Paragraph 15. If the Monitor resigns, is removed, or is otherwise unable to fulfill the Monitor's obligations as set out herein and in Attachment D, the Company shall within 20 business days recommend a pool of three qualified Monitor candidates from which the Office will choose a replacement, following the process outlined above.

17. The Monitor's term shall be 24 months from the date on which the Monitor is retained by the Company, subject to extension or early termination as described in Paragraph 3. Notwithstanding the foregoing, the Company agrees that the Monitor's role as claims administrator shall continue for a 36-month period as set forth in Attachment F. The Monitor's powers, duties, and responsibilities, as well as additional circumstances that may support an extension of the Monitor's term, are set forth in Attachment D. The Company agrees that it will not employ or be affiliated with the Monitor or the Monitor's firm for a period of not less than two years from the date on which the Monitor's term expires, nor will the Company discuss with the Monitor or the Monitor's firm the possibility of further employment or affiliation during the Monitor's term. Upon agreement by the parties, this prohibition will not apply to other monitorship responsibilities

that the Monitor or the Monitor's firm may undertake in connection with resolutions with foreign or other domestic authorities.

Deferred Prosecution

18. In consideration of the undertakings agreed to by the Company herein, the Office agrees that any prosecution of the Company for the conduct set forth in the Statement of Facts (other than the FDCA Information, as described in Paragraph 4(e)) be and hereby is deferred for the Term. To the extent there is conduct disclosed by the Company that is not set forth in the Statement of Facts, such conduct will not be exempt from further prosecution and is not within the scope of or relevant to this Agreement.

19. The Office shall, if the Company is in full compliance with all of its obligations under this Agreement, within three months after the expiration of the Term of this Agreement set forth above in Paragraph 3, or earlier at the discretion of the Office, seek dismissal with prejudice of the Felony Information filed against the Company pursuant to Paragraph 1, and this Agreement shall expire and be of no further force and effect. The Office further agrees not to file charges in the future against the Company based on conduct described in this Agreement, the Felony Information, the FDCA Information, or the Statement of Facts. If, however, the Office determines during this three-month period that the Company breached the Agreement during the Term, as described in Paragraph 20, the Office's ability to extend the Term, as described in Paragraph 3, or to pursue other remedies, including those described in Paragraphs 20–23, remains in full effect.

Breach of the Agreement

20. If, during the Term, the Company (a) commits any felony under U.S. federal law; (b) provides in connection with this Agreement deliberately false, incomplete, or misleading information, including in connection with its disclosure of information about individual

culpability; (c) fails to abide by its plea agreement concerning the FDCA Information; (d) fails to cooperate as set forth in Paragraph 5 of this Agreement; (e) fails to implement a compliance program as set forth in Paragraphs 11–12 of this Agreement and Attachment C; (f) fails to make any reports as set forth in Paragraph 13 of this Agreement and Attachment D; or (g) otherwise fails to completely perform or fulfill each of the Company's obligations under the Agreement and its duties to the Monitor, regardless of whether the Office becomes aware of such a breach after the Term is complete, the Company shall thereafter be subject to prosecution for any federal criminal violation of which the Office has knowledge, including, but not limited to, the charges in the Felony Information described in Paragraph 1, which may be pursued by the Office in the U.S. District Court for the District of Massachusetts or any other appropriate venue. Determination of whether the Company has breached the Agreement and whether to pursue prosecution of the Company shall be in the Office's sole discretion. Any such prosecution may be premised on information provided by the Company or its personnel. Any such prosecution relating to the conduct described in the Statement of Facts or relating to conduct known to the Office prior to the Effective Date of this Agreement that is not time-barred by the applicable statute of limitations on the Effective Date of this Agreement may be commenced against the Company, notwithstanding the expiration of the statute of limitations, between the Effective Date and the expiration of the Term plus one year. By signing this Agreement, the Company agrees that the statute of limitations with respect to any such prosecution that is not time-barred on the Effective Date of this Agreement shall be tolled for the Term plus one year. In addition, the Company agrees that the statute of limitations as to any violation of U.S. federal law that occurs during the Term will be tolled from the date upon which the violation occurs until the earlier of the date upon which the Office is made

aware of the violation or the duration of the Term plus five years, and that this period shall be excluded from any calculation of time for purposes of the application of the statute of limitations.

21. In the event the Office determines that the Company has breached this Agreement, the Office agrees to provide the Company with written notice of such alleged breach prior to instituting any prosecution resulting from such breach. Within 15 calendar days of receipt of such notice, unless the government agrees to a different period, the Company shall have the opportunity to respond to the Office in writing to explain the nature and circumstances of such alleged breach, as well as the actions the Company has taken to address and remediate the situation, which explanation the Office shall consider in determining whether to pursue prosecution of the Company. The parties expressly understand and agree that if the Company fails to make the above-noted presentation within such period, it shall be presumed that the Company is in willful and material breach of this Agreement. The parties further understand and agree that the Office's exercise of discretion under this paragraph is not subject to review in any court or tribunal outside the Department of Justice and the Office.

22. In the event that the Office determines that the Company has breached this Agreement: (a) all statements made by or on behalf of the Company to the Office or to the Court and any testimony given by the Company before a grand jury, a court, or any tribunal, or at any legislative hearings, whether prior or subsequent to this Agreement, and any leads derived from such statements or testimony, shall be admissible in evidence in any and all criminal proceedings brought by the Office against the Company; and (b) the Company shall not assert any claim under the United States Constitution, Rule 11(f) of the Federal Rules of Criminal Procedure, Rule 410 of the Federal Rules of Evidence, or any other federal rule that any such statements or testimony made by or on behalf of the Company prior or subsequent to this Agreement, or any leads derived

therefrom, should be suppressed or are otherwise inadmissible. The decision whether conduct or statements of any current director, officer, or employee, or any person acting on behalf of, or at the direction of, the Company, will be imputed to the Company for the purpose of determining whether the Company has violated any provision of this Agreement shall be in the sole discretion of the Office.

23. The Company acknowledges that the Office has made no representations, assurances, or promises concerning what sentence may be imposed by the Court if the Company breaches this Agreement and this matter proceeds to judgment. The Company further acknowledges that any such sentence is solely within the discretion of the Court and that nothing in this Agreement binds or restricts the Court in the exercise of such discretion.

Sale, Merger, or Other Change in Corporate Form of Company

24. Except as may otherwise be agreed by the parties in connection with a particular transaction, the Company agrees that in the event that, during the Term, it undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to the Company's operations, or to the operations of any parent company or subsidiaries involved in the conduct described in the Statement of Facts, as they exist as of the Effective Date of this Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in this Agreement. The purchaser or successor in interest must also agree in writing that the Office's ability to determine a breach under this Agreement is applicable in full force to that entity. The Company agrees that the failure to include these provisions in the transaction will make any such transaction null and void. The Company shall provide notice to the

Office at least 30 business days prior to undertaking any such sale, merger, transfer, or other change in corporate form. The Office shall notify the Company prior to such transaction (or series of transactions) if the Office determines that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of this Agreement. At any time during the Term the Company engages in a transaction(s) that has the effect of circumventing or frustrating the enforcement purposes of this Agreement, the Office may deem it a breach of this Agreement pursuant to Paragraph 20 of this Agreement. Nothing herein shall restrict the Company from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of this Agreement, as determined by the Office.

Insolvency Proceedings

25. The Company agrees that in the event that, during the Term, the Company or a third party commences a case, proceeding, or other action under any law relating to bankruptcy, insolvency, reorganization, or relief of debtors seeking any order for relief of the Company's debts, or to adjudicate the Company as bankrupt or insolvent; or seeking appointment of a receiver, trustee, custodian, or other similar official for the Company or for all or any substantial part of the Company's assets (collectively an "Insolvency Proceeding") or if the Company's obligations under this Agreement are avoided for any reason, including but not limited to, through the exercise of a trustee's avoidance powers under the Bankruptcy Code in an Insolvency Proceeding or in any other case, proceeding or action:

a. The Office, at its sole option, may subject the Company to prosecution for any federal criminal violation of which the Office has knowledge, including, but not limited to,

the charges in the Felony Information described in Paragraph 1, pursuant to the terms further set forth in Paragraphs 20–23 of this Agreement.

b. The Company shall take such actions as may be reasonably necessary or appropriate in an Insolvency Proceeding to ensure the Company will be able to comply with its obligations under this Agreement, including, without limitation, assuming its obligations under this Agreement and any agreements required pursuant to Paragraphs 14–17, including any agreements with the Monitor.

c. The terms of Paragraph 24 of this Agreement shall apply to any sale, merger, or other change in corporate form effectuated through an Insolvency Proceeding, including a sale of all or substantially of the Company's assets.

d. Any Definitive Documents[1] related to an Insolvency Proceeding shall be consistent in all material respects with this Agreement and shall not in any manner, by their terms, contain any provisions that amend, modify, supplement, supersede, or conflict with any of the provisions of this Agreement. Any Definitive Documents related to an Insolvency Proceeding shall be in form and substance reasonably acceptable to the United States.

e. In any Insolvency Proceeding in which this Agreement is not assumed and the Company's criminal fine and forfeiture obligations under the plea agreement concerning the FDCA Information are not otherwise paid in full, the United States shall be entitled to an

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[1] Definitive Documents means all material agreements, schedules, and judicial or regulatory orders related to an Insolvency Proceeding that are necessary to implement this Agreement or materially affect this Agreement, including without limitation any plan of reorganization or liquidation and any order confirming such plan, and any motion to sell the Company or to sell all or substantially all of the Company's assets and any order approving such sale.

undisputed, noncontingent, and liquidated claim that is not subject to reconsideration or subordination against the Company for the then-unpaid balance of the criminal fine and forfeiture.

f. The Company shall not argue or otherwise contend in an Insolvency Proceeding that the United States' claim, action, or proceeding with respect of the matters covered by this Agreement is subject to an automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1).

g. The Company shall not argue that the dedicated bank account described in Paragraph 6 of this Agreement is property of the estate or that any agreement with respect to such account is an executory contract. Further, the Company shall not argue or otherwise contend in an Insolvency Proceeding that distributions from the dedicated bank account pursuant to Paragraphs 14–17 of this Agreement are subject to the automatic stay and, to the extent necessary, consents to relief from the automatic stay for cause under 11 U.S.C. § 362(d)(1).

26. The Company's obligations under this Agreement may not be avoided pursuant to 11 U.S.C. § 547 or 11 U.S.C. § 548(a)(1), and the Company shall not argue or otherwise take the position in any Insolvency Proceeding or in any other case, proceeding, or action that: (i) the Company's obligations under this Agreement may be avoided under 11 U.S.C. § 547; (ii) the mutual promises, covenants, and obligations set forth in this Agreement do not constitute a contemporaneous exchange for new value given to the Company; or (iii) the mutual promises, covenants, and obligations set forth herein are not intended to and do not, in fact, represent a reasonably equivalent exchange of value or that such mutual promises, covenants, and obligations are intended to hinder, delay, or defraud any entity to which the Company was or became indebted to on or after the date of this Agreement, within the meaning of 11 U.S.C. § 548(a)(1).

27. In evaluating whether to execute this Agreement, the Company and the Office warrant that the mutual promises, covenants, and obligations set forth herein constitute a contemporaneous exchange for new value given to the Company, within the meaning of 11 U.S.C. § 547(c)(1), and the Company and the Office conclude that these mutual promises, covenants, and obligations do, in fact, constitute such a contemporaneous exchange. Further, the Company and the Office warrant that the mutual promises, covenants, and obligations set forth herein are intended to and do, in fact, represent a reasonably equivalent exchange of value that is not intended to hinder, delay, or defraud any entity to which the Company was or became indebted to on or after the date of this transfer, within the meaning of 11 U.S.C. § 548(a)(1).

28. The Company shall provide notice to the Office at least 30 business days prior to commencing an Insolvency Proceeding.

Public Statements by Company

29. The Company expressly agrees that it shall not, through present or future attorneys, officers, directors, employees, agents, or any other person authorized to speak for the Company make any public statement, in litigation or otherwise, contradicting the acceptance of responsibility by the Company set forth above or the facts described in the Statement of Facts. Any such contradictory statement shall, subject to cure rights of the Company described below, constitute a breach of this Agreement, and the Company thereafter shall be subject to prosecution as set forth in Paragraphs 20–23 of this Agreement. The decision whether any public statement by any such person contradicting a fact contained in the Statement of Facts will be imputed to the Company for the purpose of determining whether it has breached this Agreement shall be at the sole discretion of the Office. If the Office determines that a public statement by any such person contradicts in whole or in part a statement contained in the Statement of Facts, the Office shall so

notify the Company, and the Company may avoid a breach of this Agreement by publicly repudiating such statement(s) within five business days after notification. The Company shall be permitted to raise defenses and to assert affirmative claims in other proceedings relating to the matters set forth in the Statement of Facts provided that such defenses and claims do not contradict, in whole or in part, a statement contained in the Statement of Facts. This Paragraph does not apply to any statement made by the Company in litigation against its former employees, or made by any present or former officer, director, employee, or agent of the Company in the course of any criminal, regulatory, or civil case initiated against such individual, unless such individual is speaking on behalf of the Company.

30. The Company agrees that if it, its parent company, or any of its direct or indirect subsidiaries issues a press release or holds any press conference in connection with this Agreement, the Company shall first consult with the Office to determine (a) whether the text of the release or proposed statements at the press conference are true and accurate with respect to matters between the Office and the Company; and (b) whether the Office has any objection to the release.

31. The Office agrees, if requested, to bring to the attention of law enforcement and regulatory authorities the facts and circumstances relating to the nature of the conduct underlying this Agreement, including the nature and quality of the Company's cooperation and remediation. By agreeing to provide this information to such authorities, the Office is not agreeing to advocate on behalf of the Company, but rather is agreeing to provide facts to be evaluated independently by such authorities.

Publication

32. Within 10 business days of the Effective Date of this Agreement, the Company agrees to make the Information and this Agreement available to the public on its website in a

conspicuous location to the Office's reasonable satisfaction for 24 months after the Effective Date of this Agreement.

Limitations on Binding Effect of Agreement

33. This Agreement is binding on the Company and the Office but specifically does not bind any other component of the Department of Justice, other federal agencies, or any state, local, or foreign law enforcement or regulatory agencies, or any other authorities, although the Office will bring the cooperation of the Company and its compliance with its other obligations under this Agreement to the attention of such agencies and authorities if requested to do so by the Company.

Notice

34. Unless otherwise directed by the Office in writing, any notice to the Office under this Agreement shall be given by personal delivery by a recognized delivery service, or registered or certified mail, addressed to:

Chief, Health Care Fraud Unit
U.S. Attorney's Office for the District of Massachusetts
John Joseph Moakley Federal Courthouse
One Courthouse Way
Boston, MA 02210

35. Any notice to the Company under this Agreement shall be given by personal delivery, overnight delivery by a recognized delivery service, or registered or certified mail, addressed to:

Legal Department
Magellan Diagnostics, Inc.
101 Billerica Avenue
North Billerica, MA 01862

Adam J. Hollingsworth
Jones Day
901 Lakeside Avenue
Cleveland, OH 44114

Complete Agreement

36. This Agreement, including its attachments, sets forth all the terms of the agreement between the Company and the Office. No amendments, modifications, or additions to this Agreement shall be valid unless they are in writing and signed by the Office, the attorneys for the Company, and a duly authorized representative of the Company.

* * *

FOR THE UNITED STATES ATTORNEY'S OFFICE
FOR THE DISTRICT OF MASSACHUSETTS

Date: 5/21/24

JOSHUA S. LEVY
Acting United States Attorney

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Assistant U.S. Attorneys

FOR MAGELLAN DIAGNOSTICS, INC.

Date: 5/21/24

By: ______________________
EMERSON C. MOSER
Senior Vice President and General Counsel
Magellan Diagnostics, Inc.

Date: ______________________

By: ______________________
ADAM J. HOLLINGSWORTH
Counsel for Magellan Diagnostics, Inc.
Jones Day

COMPANY OFFICER'S CERTIFICATE

I have read this Agreement and carefully reviewed every part of it with outside counsel for Magellan Diagnostics, Inc. (the "Company"). I understand the terms of this Agreement and voluntarily agree, on behalf of the Company, to each of its terms. Before signing this Agreement, I consulted outside counsel for the Company. Counsel fully advised me of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

I have carefully reviewed the terms of this Agreement with the Board of Directors of the Company. I have advised and caused outside counsel for the Company to advise the Board of Directors fully of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement.

No promises or inducements have been made other than those described in this Agreement. Furthermore, no one has threatened or forced me, or to my knowledge any person authorizing this Agreement on behalf of the Company, in any way to enter into this Agreement. I am also satisfied with outside counsel's representation in this matter. I certify that I am the Senior Vice President and General Counsel for the Company and that I have been duly authorized by the Company to execute this Agreement on behalf of the Company.

MAGELLAN DIAGNOSTICS, INC.

Date: 5/21/24

By: ______________________

EMERSON C. MOSER
Senior Vice President and General Counsel
Magellan Diagnostics, Inc.

CERTIFICATE OF COUNSEL

I am counsel for Magellan Diagnostics, Inc. (the "Company") in the matter covered by this Agreement. In connection with such representation, I have examined relevant Company documents and have discussed the terms of this Agreement with the Company Board of Directors. Based on our review of the foregoing materials and discussions, it is my opinion that the representative of the Company signing this Agreement has been duly authorized to enter into this Agreement on behalf of the Company and that this Agreement has been duly and validly authorized, executed, and delivered on behalf of the Company and is a valid and binding obligation of the Company. Further, I have carefully reviewed the terms of this Agreement with the Board of Directors and the Senior Vice President and General Counsel of the Company. I have fully advised them of the rights of the Company, of possible defenses, of the Sentencing Guidelines' provisions, and of the consequences of entering into this Agreement. To my knowledge, the decision of the Company to enter into this Agreement, based on the authorization of the Board of Directors, is an informed and voluntary one.

Date: 5/21/2024

By: ______________________
ADAM J. HOLLINGSWORTH
Jones Day
Counsel for Magellan Diagnostics, Inc.

ATTACHMENT A

STATEMENT OF FACTS

The following Statement of Facts is incorporated by reference in the Deferred Prosecution Agreement (the "Agreement") between the United States Attorney's Office for the District of Massachusetts (the "Office") and defendant Magellan Diagnostics, Inc. ("Magellan" or the "Company"). The Company hereby agrees and stipulates that the following information is true and accurate. The Company admits, accepts, and acknowledges that it is responsible for the acts of its officers, directors, employees, and agents as set forth below. Should the Office pursue the prosecution that is deferred by the Agreement, the Company agrees that it will neither contest the admissibility of, nor contradict, this Statement of Facts in any such proceeding. The following facts took place in or about and between 2013 and 2018 (the "relevant time period"), unless otherwise noted, and the Company agrees that these facts establish beyond a reasonable doubt the charges set forth in the Felony Information attached to the Agreement.

General Allegations

1. MAGELLAN, headquartered in Billerica, MA, was a medical device company that sold products for detecting lead levels and lead poisoning in the blood of children and adults. MAGELLAN was privately owned by venture capital investors until March 2016, when it was acquired by Meridian Bioscience, Inc., for $66 million.

2. Amy Winslow was an individual residing in Needham Heights, Massachusetts. Winslow was MAGELLAN's President and Chief Executive Officer from in or around 2011 through in or around 2018.

3. Mohammad Hossein Maleknia was an individual residing in North Andover, Massachusetts. Maleknia was MAGELLAN's Chief Operating Officer and Vice President of Operations from in or around 2012 through in or around 2021.

4. Reba Daoust was an individual residing in Amesbury, Massachusetts. Daoust was MAGELLAN's Director of Quality Assurance and Regulatory Affairs from in or around 2012 through in or around July 28, 2017.

5. "Employee A" was a manager in MAGELLAN's Research and Development department.

6. "Employee B" was a manager in MAGELLAN's Technology Development and Assessment department.

7. "Employee C" was MAGELLAN's Marketing Director.

8. "Employee D" was MAGELLAN's Product Support Manager.

9. "Employee E" was Meridian's Executive Vice President of Global Regulatory and Quality Systems.

10. MAGELLAN misled its customers and the FDA about a serious malfunction in the lead testing devices produced by MAGELLAN ("Malfunction"). By hiding the Malfunction and later deceiving customers and the FDA about when it discovered the Malfunction and its nature and extent, MAGELLAN caused an estimated tens of thousands of children and other patients to receive inaccurate lead test results.

Lead Poisoning and Blood Lead Testing

11. According to the Centers for Disease Control and Prevention (CDC), there is no safe level of lead in the blood. Lead exposure may cause irreversible lifelong physical and mental health problems, including damage to the nervous, hematopoietic, endocrine, renal, and

reproductive systems. Lead exposure may also damage children's ability to learn, ability to pay attention, and academic achievement. High levels of lead exposure attack the brain and central nervous system and may cause coma, convulsions, and even death.

12. Young children and pregnant women are most vulnerable to lead exposure because children absorb lead more easily than adults, and their growing bodies are more prone to harm. Children from low-income households and those who live in housing built before 1978 are at the greatest risk of lead exposure because those homes are more likely to contain lead-based paint and have pipes, faucets, and plumbing fixtures containing lead. Lead poisoning also disproportionately impacts refugees and other children who have resettled in the United States because of prior environmental exposure in their countries of origin.

13. Lead poisoning can be difficult to detect—signs and symptoms of lead poisoning usually do not appear until dangerously high amounts of lead have accumulated in the body. Blood lead testing is the best way to detect lead poisoning.

14. In 2012, CDC introduced a medical threshold at blood lead levels of 5 micrograms per deciliter (μg/dL) to identify children and adults who have elevated blood lead levels. At that level, CDC recommended that healthcare providers:

a. Report the test result to their state or local health department;

b. Obtain an environmental exposure history to identify potential sources of lead;

c. Arrange for an environmental investigation of the home, during which professionals would check the child's environment for possible causes of lead exposure and recommend ways to prevent further lead exposure; and

d. Provide follow-up blood lead testing at recommended intervals.

15. CDC recommended additional interventions for higher levels of lead in the blood, including the recommendation that physicians consider the need for hospitalization and chelation therapy to remove lead from the blood if the level reached 45 µg/dL.

16. State agencies promulgated different requirements and recommendations for the frequency of lead testing in children. In Massachusetts, for example, children were required to be screened once between the ages of 9–12 months, again at age 2, and then again at age 3. Children were required to be screened once more at age 4 if they lived in a high-risk community or in a high-risk environment. The Centers for Medicare and Medicaid Services (CMS) required children enrolled in Medicaid to be tested for lead at ages 12 and 24 months, or ages 24–72 months if they had never been tested.

MAGELLAN's Lead-Testing Devices

17. MAGELLAN produced a family of instruments for blood lead analysis using a method called anodic stripping voltammetry. Those devices included, but were not limited to, LeadCare II, LeadCare Ultra, and LeadCare Plus (collectively the "LeadCare Devices").

18. LeadCare II was released in 2006 and was the only point-of-care lead testing device, which means it was cleared by the United States Food and Drug Administration (FDA) for use in non-laboratory settings such as doctors' offices and clinics. The LeadCare II device could be used to test blood samples drawn from a vein ("venous" samples) and samples drawn from a fingerstick (or heelstick). Most LeadCare II tests were conducted on fingerstick samples; MAGELLAN estimated that approximately 5–8% of LeadCare II users conducted testing with venous blood samples. In 2017, MAGELLAN estimated LeadCare II devices were used to conduct 2.5 million blood lead tests per year—accounting for more than half of all lead tests

conducted in the United States. The LeadCare II system was responsible for a substantial majority of MAGELLAN's revenues.

19. LeadCare Ultra was released in 2013 and was designed for use at medium and large hospitals and reference labs. LeadCare Ultra could be used to test both fingerstick blood samples and venous blood samples but was predominantly used for venous blood samples. In 2017, MAGELLAN estimated LeadCare Ultra devices were used to conduct 420,000 blood lead tests per year.

20. LeadCare Plus was released in 2015 and was designed for use at small hospitals and reference labs. LeadCare Plus could be used to test both fingerstick blood samples and venous blood samples but was predominantly used for venous blood samples. In 2017, MAGELLAN estimated that LeadCare Plus devices were used to conduct 40,000 blood lead tests per year.

FDA and FDCA

21. FDA was responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices—including diagnostic testing devices—were safe and effective. Under its statutory mandate, FDA regulated the manufacture, processing, packing, labeling, and shipment in interstate commerce of medical devices.

22. The Federal Food, Drug, and Cosmetic Act (FDCA), among other things, governed the manufacture and interstate distribution of medical devices for human use, as codified at 21 U.S.C. §§ 301 et seq.

23. The FDCA required medical devices to bear labeling that is not false or misleading. A device was deemed to be "misbranded" under 21 U.S.C. § 352(a) if its labeling was false or misleading.

24. The FDCA and its implementing regulations required device manufacturers to submit pre-market notifications to the FDA at least 90 days before medical devices were introduced into interstate commerce for commercial distribution. Pre-market notifications were required when a device that was already on the market was about to be significantly changed or modified in design or intended use, and the change could significantly affect the safety or effectiveness of the product. 21 C.F.R. § 807.81. A device was deemed to be "misbranded" under 21 U.S.C. § 352(o) if a device manufacturer failed to submit necessary pre-market notification.

25. The FDCA and its implementing regulations provided a mechanism that allowed FDA, and others, to identify and monitor adverse events and malfunctions involving medical devices. Medical device reports (MDRs) were one of the post-market surveillance tools that FDA used to monitor device performance and detect potential device-related safety issues.

26. Medical device manufacturers were required to submit MDRs within 30 calendar days after becoming aware of a device malfunction pursuant to 21 U.S.C. § 360i(a) and 21 CFR Part 803 if the malfunction was likely to cause or contribute to serious injury or death if it recurred. Device malfunctions were defined as a failure of the device to perform as intended or meet its performance specifications, including all claims made in the device labeling under 21 CFR § 803.3.

27. The FDCA and its implementing regulations required device manufacturers to notify the FDA about device corrections—which included modifications, adjustments, and relabeling—within 10 working days of initiating the device correction if the correction was initiated to reduce a risk to health posed by the device. 21 CFR § 806.10.

28. A device was deemed to be "misbranded" under 21 U.S.C. § 352(t)(2) if the manufacturer failed or refused to file any material or information required by or under 21 U.S.C. § 360i, including an MDR or a device correction.

29. The FDCA prohibited the introduction, or causing the introduction, of misbranded medical devices into interstate commerce, pursuant to 21 U.S.C. § 331(a).

MAGELLAN's Sale Efforts

30. Before MAGELLAN was purchased by Meridian in or around March 2016, MAGELLAN was an investor-owned medical device company, which had been owned by a group of venture capital firms—including a majority owner, "Investor A"—for approximately seven years. MAGELLAN's Board of Directors was almost exclusively made up of representatives from Investor A and the other venture capital firms that owned MAGELLAN. The ultimate goal of MAGELLAN's investors and Board of Directors was to grow MAGELLAN's value and to position MAGELLAN for sale, which included developing new products such as LeadCare Ultra, LeadCare Plus, and another product MAGELLAN tried to develop, PediaStat, and strengthening sales of MAGELLAN's primary revenue-producer, LeadCare II.

31. MAGELLAN's latest effort to market the company for sale began in or around 2015, and MAGELLAN received a letter of intent from Meridian with a purchase price of $62.5 million on or about January 21, 2016. During Meridian's due diligence, MAGELLAN disclosed information about the Malfunction affecting LeadCare Ultra, but MAGELLAN withheld material information about the nature, extent, and discovery of the Malfunction, failed to disclose that it had made false and misleading statements to its customers and the FDA about the

Malfunction in LeadCare Ultra, and failed to disclose that the Malfunction also affected LeadCare II, MAGELLAN'S highest selling product.

32. MAGELLAN was acquired by Meridian for $66 million in or around March 2016. The acquisition price was more than $15 million higher than the next highest purchase offer received for MAGELLAN. After MAGELLAN was acquired by Meridian, Winslow received a bonus of approximately $2 million, and Maleknia received a bonus of approximately $448,000.

LeadCare Ultra Application for FDA Clearance

33. In or around November 2012, MAGELLAN sought clearance from FDA to introduce into the market its newly developed LeadCare Ultra device. MAGELLAN submitted a Traditional 510(k) application to FDA (the "LeadCare Ultra 510(k) application"), which claimed that the LeadCare Ultra was substantially equivalent to the already-cleared LeadCare II device. In its application, MAGELLAN described LeadCare Ultra as "an *in vitro* diagnostic device that relies on electrochemistry . . . and a unique sensor to detect lead in whole blood . . . When a sample of whole blood is mixed with Treatment Reagent (a diluted solution of hydrochloric acid), [lead is separated from the red blood cells] and lead becomes available for detection."

34. MAGELLAN's LeadCare Ultra 510(k) application contained performance testing comparing LeadCare Ultra's performance to a reference method for testing blood lead concentrations using standardized blood samples, donor blood, and human and bovine blood spiked to certain lead concentrations. The reference method was called graphite furnace atomic absorption spectrometry (GFAAS). MAGELLAN's performance testing also included a clinical study in which 394 blood samples were collected. Of the 394 blood samples collected, 148 samples were within range (1.9-65 μg/dL). MAGELLAN represented to FDA that the clinical data "met the acceptance criteria, defined as average bias within the range of ±2 μg/dL in the concentration range of 1.9 to 10 μg/dL and ±10% for concentrations above 10 μg/dL."

35. On or about January 14, 2013, FDA issued a Hold Memo for MAGELLAN's LeadCare Ultra 510(k) application, which noted several deficiencies and requested additional studies and documentation. The Hold Memo included the following request:

> In your labeling, [you] provide system operating ranges for LeadCare Ultra system including, altitudes (up to 8,000 feet [] above sea level), relative humidity (12% - 80% …) and temperature (61-82 °F []). However, you did not provide operating range studies in your submission. Please provide operating range study protocol including acceptance criteria and study summary to support your claim.

<u>Discovery of LeadCare Malfunction</u>
(June 2013)

36. While conducting the temperature and humidity studies requested by FDA in the Hold Memo, MAGELLAN discovered a malfunction affecting the LeadCare Ultra device (the "Malfunction"). The Malfunction tended to result in lower blood lead values when the blood sample was tested shortly after it was mixed with treatment reagent (sometimes referred to as "T0" for 0 minutes of incubation) and higher blood lead values if the blood-treatment reagent mixture were allowed to sit, or "incubate," for several hours or days before testing (sometimes referred to as "T[amount of incubation time]," such as "T4" for four hours of incubation time or "T24" for 24 hours of incubation time). When the Malfunction occurred, the lower blood lead value was often below that of the GFAAS device for the same sample. With incubation, the higher blood lead value was often closer to that of GFAAS but could be higher than GFAAS.

37. The Malfunction was first observed in or around June 27, 2013, when a MAGELLAN employee performed the temperature and humidity studies requested by FDA. This employee forwarded the results of this study to Daoust. The temperature and humidity studies measured blood lead levels at different temperature and humidity conditions (a) shortly

after mixing the blood sample with treatment reagent and (b) after letting the blood-treatment reagent mixture incubate for one to two days.

38. After reviewing the results of the temperature and humidity studies, Daoust sent an email to several MAGELLAN employees, including Employee A and Employee B, with the subject line "HELP," writing: "More to come … later. very stressed … Results across all sensors, and 2 Ultra's consistently low." Daoust noted that the blood lead results were "consistently low," but when the same samples were tested a day later, they were within the range of MAGELLAN's acceptance criteria. Daoust asked, "Has there ever been studies at 0 hours, 12, 24, 48 hours, etc.[?]" On or about June 27, 2013, Employee A responded to Daoust, "Yes a time study has been done with carbon in [treatment reagent] … Study was done in 2007." Daoust responded on or about June 28, 2013, "I hope this turns out to be nothing….2007 was 8 years ago." Daoust informed Winslow and Maleknia, among others, at least as early as June 28, 2013 about the Malfunction affecting LeadCare Ultra.

39. MAGELLAN did not notify FDA about the failed results of MAGELLAN's temperature and humidity studies that showed the Malfunction. Instead, MAGELLAN responded to the pertinent portion of FDA's Hold Memo on or about July 10, 2013 by reporting results from a different temperature and humidity study, which confirmed that the LeadCare Ultra device operated at different temperature and humidity conditions, but did not contain any blood lead measurements. MAGELLAN explained that its submitted temperature and humidity study, "demonstrated that the currents and voltages/potentials used to perform the electrochemical blood lead assay/test remained within the required ±2% operating level across the tested conditions, for all analyzer channels." MAGELLAN's submission to FDA did not mention the Malfunction.

FDA Clearance of LeadCare Ultra
(August 2013)

40. FDA—unaware of the Malfunction—cleared the LeadCare Ultra device for marketing and distribution on or about August 20, 2013. In its clearance letter, FDA emphasized, "We remind you, however, that the device labeling must be truthful and not misleading."

41. The label for the FDA-cleared Ultra device made accuracy claims based on its method comparison study, in which the average bias, or average difference from GFAAS, was less than one microgram per deciliter at each blood lead level tested, and the negative bias from GFAAS was 1% or less at each blood level tested, as shown below:

ACCURACY:
The accuracy of the LeadCare Ultra Blood Lead Testing System was determined by a Method Comparison study at two hospital laboratory sites. Three hundred ninety-four (394) results, from a combination of spiked and unspiked blood samples, were generated. One hundred forty-eight results were within the claimed analytical range of 1.9 – 65.0 µg/dL. The LeadCare Ultra results were plotted versus the results obtained by the Reference Method, GFAAS. The LeadCare Ultra average bias from GFAAS and the scatter plot of LeadCare Ultra vs. GFAAS results, with the linear regression, are provided in Table 2 and Graph 1, respectively.

Table 2: LeadCare Ultra Average Bias from GFAAS

GFAAS (µg/dL)	Predicted LeadCare Ultra (µg/dL)	Avg. Bias (µg/dL)	Bias (%)
1.90	1.95	0.05	2.4%
5.00	5.01	0.01	0.2%
10.00	9.96	-0.04	-0.4%
20.00	19.85	-0.15	-0.7%
30.00	29.74	-0.26	-0.9%
40.00	39.64	-0.36	-0.9%
50.00	49.53	-0.47	-0.9%
60.00	59.42	-0.58	-1.0%
65.00	64.37	-0.63	-1.0%

42. MAGELLAN's method comparison study, however, did not control for the amount of time that the blood-treatment reagent incubated before testing, which is to say that the laboratories participating in the method comparison study were free to run the tests at any time after mixing the blood sample and treatment reagent as permitted by the LeadCare Ultra label. The LeadCare Ultra label's instructions for use stated in part: "After mixing the blood with the Treatment Reagent, analyze it in less than 48 hours if stored at room temperature. If stored

refrigerated, analyze within 7 days." Thus, if the normal workflow of these laboratories included sufficient incubation time after mixing, the study was unlikely to show the effects of the Malfunction.

43. The label for the FDA-cleared LeadCare Ultra device also stated:

> Childhood lead poisoning is a major, preventable problem in the United States. Numerous studies have shown that exposure to lead can result in damage to the nervous, hematopoietic, endocrine, renal, and reproductive systems causing lifelong physical and mental health problems. Children are particularly susceptible to the effects of lead as their nervous systems are still developing.
>
> In 2012, based on the increased body of evidence demonstrating there is no safe level of lead in the blood, experts established a new reference value to identify children who have elevated blood lead levels (BLL). According to the Centers for Disease Control (CDC) website (www.cdc.gov/nceh/lead), this level is based on the U.S. population of children ages 1-5 years who are in the top 2.5% of children when tested for lead in their blood (when compared to children who are exposed to more lead than most children). Currently this reference value is 5 µg/dL.

Confirmation of the Malfunction and Delayed Release of LeadCare Ultra (September 2013 – December 2013)

44. Despite its original plans to do so, MAGELLAN did not release LeadCare Ultra to the market shortly after FDA clearance because of concerns about the Malfunction. From in or around August 2013 until in or around December 2013, MAGELLAN designed and conducted multiple studies comparing LeadCare Ultra test results measured (a) immediately after blood samples were mixed with treatment reagent and (b) after allowing the blood-treatment reagent to incubate for various time periods ("the 2013 Malfunction Studies"). While the Malfunction did not appear in every experiment, the 2013 Malfunction Studies repeatedly showed that the Malfunction occurred when testing various types of blood samples, at various lead concentrations, and using various sensors and treatment reagents. Conclusions from some of the 2013 Malfunction Studies included:

a. "[F]resh human samples, unspiked and spiked [samples] all increased in [lead] value during [a] 4 day period with the exception of the [sample spiked to the lead concentration of 50 µg/dL.]"

b. "There is a reproducible trend of increased [lead] signal with increased Sample/Treatment reagent incubation time … Trend is evident: On multiple sensor lots at varying degrees [and with] multiple blood samples … Can create false lows or false highs[.] No one incubation time mitigates the false lows or highs. Although 30 mins looks favorable … Per [Daoust], change of instruction to include incubation time would require resubmitting data to FDA."

c. "Sample/Treatment Reagent Preparations incubated at either Room Temperature or Refrigerated confirms the trend of increased [lead result] from T0 to T 24."

d. "This phenomenon is apparent for all three blood samples tested."

e. "This phenomenon is most evident when assessing the T0 vs. T24 graphs or the Difference Plots of difference from either T0 or GFAAS."

f. "The results of this study demonstrate that, in most cases, overnight incubation of the sample/Treatment Reagent preparations lead to higher LeadCare Ultra results than immediately [testing] the sample after mixing in the Treatment Reagent."

g. "Additionally, when samples that differed ± 2µg/dL between immediate vs. overnight incubation were [retested], the value obtained in the [retest] was many times greater than that obtained after overnight incubation."

45. Despite knowing that the Malfunction could cause inaccurate test results, MAGELLAN released LeadCare Ultra for sale to customers in or around December 2013.

MAGELLAN did not notify customers or FDA in 2013 that the Malfunction could cause false lows and false highs, especially if testing was conducted immediately after mixing blood samples with treatment reagent.

46. In or around June 2014, Employee A and Employee B briefed MAGELLAN executives, including Winslow, Maleknia, and Daoust, on a MAGELLAN study using LeadCare Ultra to test lead levels, without incubation, in 10 blood samples collected from employees at battery manufacturing facilities (battery workers) who were exposed to high levels of lead in their occupation. The slide deck from this briefing warned that: "[A]ll 10 samples demonstrated extremely negative bias vs GFAAS;" there was an "increased signal with increased incubation time;" there was an "inherent risk for false negative blood lead results;" and MAGELLAN "must identify root cause."

<u>Discovery and Confirmation of the Malfunction in LeadCare II</u>
(2013—November 2014)

47. During the 2013 Malfunction Studies, MAGELLAN conducted studies to determine whether the Malfunction affected LeadCare II sensors and treatment reagent as well as LeadCare Ultra.

a. On or about October 23, 2013, for example, MAGELLAN tested blood samples after they incubated in LeadCare Ultra treatment reagent and LeadCare II treatment reagent. The results showed that the blood lead levels increased after overnight incubation in both the LeadCare Ultra and LeadCare II treatment reagent. MAGELLAN's report concluded, "Increased signal after overnight incubation in LCII [treatment reagent] suggests this is a general phenomenon not related to the carbon in the Ultra [treatment reagent.]"

b. On or about November 13, 2013, MAGELLAN conducted a study to "understand if the [LeadCare Ultra] correlation issues are isolated to [LeadCare Ultra] or if [LeadCare II] … sensors show the same results." The study found:

> Both [LeadCare Ultra] and [LeadCare II] using their [respective] treatment reagents produced the same data for the 23 blood samples. … Both [LeadCare II] and [LeadCare Ultra] again produced the same results after analyzing the same samples after 24 hours. The bias after overnight incubation for [LeadCare II] and [LeadCare Ultra] was in most cases lower than that obtained with immediate assay. … There is a negative bias in this group of battery workers blood and all three products [LeadCare II, LeadCare Ultra, and a prior generation LeadCare Device] exhibit this negative bias. The bias for [LeadCare II] and [LeadCare Ultra] are similar, however less bias is observed with [the prior generation LeadCare Device] sensor.

48. Despite knowing that the Malfunction could cause inaccurate LeadCare II test results, MAGELLAN did not continue conducting experiments to confirm, analyze, and quantify the effect of the Malfunction on LeadCare II, which was MAGELLAN's top-selling product responsible for a substantial majority of MAGELLAN's revenue. In or around Spring of 2015, Winslow directed Employee B not to include LeadCare II in a Malfunction study so that the company could maintain "plausible deniability."

49. Prior to November 2016, MAGELLAN did not inform customers and FDA that the Malfunction was likely to cause inaccurate test results when LeadCare II was tested using venous samples.

<u>LeadCare Ultra Customer Complaints</u>
(August 2014—November 2014)

50. Beginning in or around August 2014, certain LeadCare Ultra customers independently discovered the Malfunction after they observed inaccurate and changing lead test results. On or about August 13, 2014, MAGELLAN received complaints from two customers, "Hospital A" in Baltimore, Maryland, and "Medical Laboratory A" in Washington, D.C. Both

Hospital A and Medical Laboratory A complained about receiving unexpectedly low test results when samples were tested immediately after being mixed with treatment reagent, as the label allowed. Hospital A and Medical Laboratory A found that the lead test result was higher if the sample was tested an hour after the sample was mixed with treatment reagent. Employee D, MAGELLAN's Product Support Manager, summarized the customer complaints in an email to Daoust, Maleknia, and others. In response, Daoust wrote, "Here we go again............please call a meeting together so we can discuss this. This is what we were afraid of."

51. MAGELLAN received other complaints from customers through in or about October 2014. Customers reported that they were receiving inaccurate lead test results, test results that were significantly lower than the expected value, and false lows that were below CDC's medical threshold of 5 μg/dL while the value on reference methods was greater than 5 μg/dL. MAGELLAN did not tell customers that MAGELLAN had been aware of the Malfunction for more than a year. On the contrary, MAGELLAN directed its employees to provide materially false and misleading responses to complaining customers by, among other things, stating that MAGELLAN was surprised to learn about the Malfunction from its customers. For instance, after Employee D advised the first complaining customer to incubate after mixing the sample and reagent, Daoust responded to the same customer with knowingly and materially false and misleading information, saying: "Just to clarify, [Employee D]'s suggestion that you extend the incubation time is based exclusively on the results you have shared with us. To date, we have not been able to replicate the large differences you have observed based upon incubation time." Daoust continued, "[w]e are continuing our investigation in-house to find the root cause, and to determine if there is an aging issue that will require a change [to] our instructions. Thank you for bringing this issue to our attention."

52. On or about November 24, 2014, MAGELLAN sent LeadCare Ultra customers a letter about the Malfunction (the "LeadCare Ultra Customer Letter"). The LeadCare Ultra Customer Letter advised customers to allow the blood-treatment reagent mixture to sit for a minimum of 24 hours before testing. This advice contradicted the LeadCare Ultra label, which permitted users to analyze the sample immediately after mixing the blood sample and treatment reagent and permitted users to analyze the mixture within 48 hours if the mixture was kept at room temperature or within seven days if the mixture was refrigerated.

53. The LeadCare Ultra Customer Letter also contained several materially false and misleading statements, and concealed material facts, about the Malfunction and MAGELLAN's discovery of the Malfunction, including those in bold type and italics below:

a. "This letter is to inform you of an ***infrequent occurrence*** observed with the LeadCare Ultra Blood Lead Testing System, which could impact a small percentage of your patient results." This statement was materially false and misleading because MAGELLAN had no basis for estimating the frequency of the Malfunction.

b. "This phenomenon appears to be limited to a ***small percentage*** of samples." This statement was materially false and misleading because, based on MAGELLAN's internal testing, the Malfunction had the potential to affect 100% of a customer's samples. In fact, in MAGELLAN's largest study conducted shortly before the LeadCare Ultra Customer Letter was sent, the Malfunction appeared in 100% of the samples tested at T0.

c. "We have ***recently*** identified cases where the LeadCare Ultra System underestimates the lead concentration of some blood samples when the sample is analyzed immediately." This statement was materially false and misleading because

MAGELLAN identified the Malfunction in or around June 2013 and confirmed the existence of the Malfunction in tests conducted in or around the 2013 Malfunction Studies, which concluded approximately one year before MAGELLAN sent the LeadCare Ultra Customer Letter to its customers.

d. "***We did not observe this in our clinical trials prior to the product release.***" This statement was materially false and misleading because (a) MAGELLAN's method comparison study for LeadCare Ultra did not control for the amount of time that the blood sample incubated in the treatment reagent and thus was unlikely to have revealed the Malfunction, and (b) MAGELLAN did observe the Malfunction in temperature and humidity studies requested by FDA and in the 2013 Malfunction Studies before product release.

Overdue Filing of the LeadCare Ultra MDR
(April 2015)

54. Despite the LeadCare Ultra Customer Letter, MAGELLAN did not notify FDA about (a) MAGELLAN's discovery of the Malfunction and (b) MAGELLAN's change to the LeadCare Ultra user instructions for over four months.

55. In or around March 2015, MAGELLAN engaged an outside statistician ("Consultant A") to review the results from MAGELLAN's largest study related to the Malfunction. This study had been conducted in November 2014, prior to the issuance of the LeadCare Ultra Customer Letter. Consultant A concluded that when the blood-treatment reagent was tested immediately after mixing, the test results were on average 53% below the GFAAS expected reference value. Consultant A warned that the Malfunction could cause false lows: "That is, a true value above 5 [µg/dL], would likely show up as a normal value (below [5 µg/dL]) and a value that requires emergency treatment (>45 µg/dL) might be reported well below 45

[µg/dL]." Consultant A concluded that "MAGELLAN needs to determine whether the FDA needs to be notified according to the Medical Device Reporting law (Code of Federal Regulations, title 21, part 803)."

56. In subsequent communications related to his report, Consultant A repeatedly advised MAGELLAN to report the Malfunction to FDA. In a conference call, Consultant A gave MAGELLAN an ultimatum, saying in words and substance: "If you do not tell the FDA, I will." This ultimatum prompted MAGELLAN to file an MDR for LeadCare Ultra.

57. On or about April 2, 2015, MAGELLAN submitted an MDR about the Malfunction (the "LeadCare Ultra MDR"). The LeadCare Ultra MDR contained several materially false and misleading statements and concealed material facts about the Malfunction and MAGELLAN's discovery of the Malfunction. For instance, the LeadCare Ultra MDR stated:

a. "[On March 23, 2015, b]ased on new information, a second Risk Analysis was performed…Statistical analysis of additional data revealed an increased rate of occurrence and an increased magnitude of bias with immediate running of the assay across the population of samples tested. … During our investigation [after November 2014] new data indicated the frequency of this occurrence had increased." These statements were materially false and misleading because (a) the data reviewed by Consultant A for his report was not new data, but data collected before November 2014, and (b) MAGELLAN had not received any data since then that showed an increased magnitude of bias from, or an increased rate in the occurrence of, the Malfunction. These materially false and misleading statements were made to conceal the fact that the actual

precipitating factor for MAGELLAN's decision to file the MDR was Consultant A's ultimatum.

b. "In November of [2014], we determined that blood lead results were being underestimated… We did not observe this in our clinical studies prior to product release." This statement was materially false and misleading because (a) MAGELLAN's method comparison study for LeadCare Ultra did not control for the amount of time that the blood sample incubated in the treatment reagent and thus was unlikely to have revealed the Malfunction, and (b) MAGELLAN did observe the Malfunction in temperature and humidity studies requested by FDA and in the 2013 Malfunction Studies before product release.

c. "8/13/2014 We received initial [complaints] from [Hospital A] and [Medical Laboratory A] that indicated they were getting slightly higher results when repeating the tests with the LeadCare Ultra. MAGELLAN could not confirm the differences that the customers were seeing when reviewing internal data." This statement was materially false and misleading because MAGELLAN actually identified the Malfunction in or around June 2013 and confirmed the existence of the Malfunction in the 2013 Malfunction Studies, which concluded approximately nine months before MAGELLAN received the customer complaints in August 2014.

58. MAGELLAN did not receive a response from FDA following its submission of the LeadCare Ultra MDR in April 2015.

59. In or around August 2015, MAGELLAN approved an engineering change order (ECO) that changed the LeadCare Ultra label, user guide, and website to incorporate the 24-hour incubation instruction. MAGELLAN did not notify FDA of the change to the device and product

insert, nor did FDA clear the significantly changed device. Daoust completed the ECO in a materially false and misleading way to support the conclusion that FDA clearance was not necessary, even though she was well aware that FDA clearance was needed for a significant labeling or design change such as this.

LeadCare Plus Application
(August 2014)

60. As part of MAGELLAN's corporate effort to grow its share in the lead testing market, MAGELLAN developed a new product, LeadCare Plus, which was marketed to small and medium-sized laboratories and hospitals.

61. MAGELLAN submitted a Special 510(k) application to FDA for the LeadCare Plus product in or around August 2014. Because LeadCare Plus's sensor technology and treatment reagent were substantially equivalent to those of LeadCare Ultra and LeadCare II, MAGELLAN expected that LeadCare Plus would also be affected by the Malfunction. As a result, Winslow and Maleknia directed that the method comparison study for LeadCare Plus not be run at T0, because they believed the study would fail.

62. MAGELLAN's original LeadCare Plus Special 510(k) application did not include an incubation time in the label's instructions for use. In or around May 2015, MAGELLAN resubmitted to FDA a new label for LeadCare Plus that included a 24-hour incubation time but did not alert FDA to the change in its proposed labeling or to the fact that the Malfunction was likely to affect the LeadCare Plus device. FDA cleared the LeadCare Plus in or around July 2015.

Test Tube Experiments
(2015)

63. In or around 2015, MAGELLAN scientists continued to conduct studies to identify the most likely root cause of the Malfunction, focusing on whether a substance in the

rubber stopper of commonly used test tubes made by COMPANY A interfered with the LeadCare Device sensors and caused test results to be lower than expected. MAGELLAN did not notify customers or FDA immediately of the results of their studies into the root cause of the Malfunction. Because the majority of venous blood samples analyzed by the LeadCare Devices were collected in COMPANY A test tubes, MAGELLAN did not want to prohibit the use of COMPANY A tubes. MAGELLAN continued to test incubation times and methods in the hopes of finding an alternate way of addressing the Malfunction.

64. MAGELLAN's internal testing also revealed a separate issue involving tubes manufactured by COMPANY B and marketed under the BRAND X name in or around June through August 2015. Studies indicated that LeadCare results for high lead concentration samples collected in BRAND X tubes were initially accurate, but after approximately 48 hours of incubation, the test results decreased substantially to inaccurate, unacceptably low values. MAGELLAN employees referred to this as the "BRAND X Cliff effect." MAGELLAN did not notify customers and FDA of the separate malfunction affecting BRAND X tubes.

Overdue Notification to FDA about LeadCare II Malfunction
(November 2016)

65. In or around November 2016, approximately three years after MAGELLAN discovered the Malfunction in LeadCare II treatment reagent and sensors and more than two years after conducting additional validation studies in which the Malfunction appeared in LeadCare II as well as LeadCare Ultra, MAGELLAN submitted an amendment to the LeadCare Ultra MDR disclosing that the Malfunction also affected LeadCare II (the "LeadCare II MDR"). The LeadCare II MDR and its cover letter contained materially false and misleading statements and concealed material facts about MAGELLAN's discovery of the Malfunction in LeadCare II, including the following:

a. "The original Medwatch [MDR] was submitted for the LeadCareUltra. Through extensive testing the root cause was finally isolated. Once MAGELLAN found out the root cause we retested the LeadCare II which originally did not exhibit this issue." This statement was materially false and misleading because MAGELLAN was aware that LeadCare II was affected by the Malfunction as early as in or around October and November 2013, long before it discovered the most likely root cause of the Malfunction in LeadCare Ultra.

b. "MAGELLAN Diagnostics felt that although the risk of this issue was small, out of an abundance of caution we are notifying those customers that use venous blood draw tubes only. Capillary tubes do not exhibit this phenomenon." These statements were materially false and misleading because (a) MAGELLAN was aware that the risk of this issue was not small, and (b) MAGELLAN had conducted studies of microcapillary tubes used to collect fingerstick blood samples that showed that blood lead test results from LeadCare II changed depending on incubation time.

c. "Once MAGELLAN found out the root cause we retested the LeadCare II which originally did not exhibit this issue." "Once root cause was found LeadCare II was investigated and found to have the same problem but at lesser impact." These statements in the MDR were materially false and misleading because MAGELLAN was aware that LeadCare II was affected by the Malfunction as early as in or around October and November 2013, long before it discovered the most likely root cause of the Malfunction in LeadCare Ultra.

d. "PLEASE NOTE: Capillary tubes and finger sticks do NOT exhibit this phenomenon as there are no rubber stoppers to contact the blood and leach the interfering

substance." This statement was materially false and misleading because MAGELLAN had conducted studies of microcapillary tubes used to collect fingerstick blood samples that showed that blood lead test results from LeadCare II changed depending on incubation time.

66. The LeadCare II MDR was submitted by MAGELLAN on or around November 7, 2016. However, MAGELLAN mailed the LeadCare II MDR and did not file it electronically as required by FDA. The LeadCare II MDR was not properly filed and was not received by FDA until in or around 2017.

67. On or about November 4, 2016, MAGELLAN caused a letter (the "LeadCare II Customer Letter") to be sent to laboratory customers believed to be using LeadCare II with venous samples (which accounted for approximately 8% of its customers) advising those customers to let blood-treatment reagent samples incubate for four hours before testing. MAGELLAN ensured that this letter was not sent to customers believed to be using LeadCare II with capillary samples.

The 2017 Recall

68. MAGELLAN continued to search for ways of shortening the 24-hour incubation time that they instituted for LeadCare Ultra and LeadCare Plus to address the Malfunction. On or about March 3, 2017, MAGELLAN filed a Special 510(k) with FDA to change the labels for LeadCare Ultra and LeadCare Plus to allow customers to test the blood-treatment reagent sample after just one hour if the sample was heated to 60 degrees Centigrade (the "LeadCare Ultra and LeadCare Plus Special 510(k) application").

69. Soon after receiving the LeadCare Ultra and LeadCare Plus Special 510(k) application, FDA contacted MAGELLAN with urgent questions about the Malfunction, its effect

on the precision and accuracy of LeadCare Devices, and whether MAGELLAN's data supported the proposed labeling changes.

70. One issue that FDA focused on was when MAGELLAN discovered the Malfunction, because the date of discovery determined the number of patients that could have received false test results. On or about April 20, 2017, during a call that was attended by Daoust, Maleknia, Employee A, Employee D, and a regulatory consultant for MAGELLAN ("Consultant B"), FDA asked when MAGELLAN first discovered the Malfunction. Based on input from Daoust and Maleknia before the call, and at the direction of Daoust during the call, Consultant B falsely told FDA that MAGELLAN first discovered the problem in late 2014 after receiving customer complaints and shortly before the LeadCare Ultra MDR was filed. This statement was materially false and misleading because MAGELLAN actually discovered the Malfunction in 2013.

71. FDA ultimately found that MAGELLAN's data showed that LeadCare Devices could not accurately test venous samples, regardless of MAGELLAN's recommended incubation times. In or around May 2017, FDA recommended a recall of all LeadCare Devices using venous samples and warned the public not to use LeadCare Ultra, LeadCare II, and LeadCare Plus for venous blood samples because of the Malfunction.

72. As a result of the recall, FDA also conducted an on-site inspection of MAGELLAN's facility and issued a report summarizing its findings on or about June 29, 2017. The report stated, in part:

a. "Your firm became aware that the original LeadCare Ultra design validation did not conform to the intended use as demonstrated by the study titled 'Blood in Treatment Reagent Stability Study', VP # 113, conducted in September 2013. This

study concludes that there is a 'reproducible trend of increased [lead] signal with increased Sample/Treatment Reagent incubation time.' However, your firm released the LeadCare Ultra product for commercial distribution in November 2013 without implementing a change to include incubation time."

b. "On November 24, 2014, your firm sent a 'Notice to Customers' letter instructing them to incubate the blood-treatment reagent mixture for at least 24 hours to prevent underestimation of the lead concentration of blood samples on the LeadCare Ultra system. Your firm failed to validate this incubation to ensure that the design change met the intended use of the device, as well as the needs of the user."

c. "Your firm failed to identify potential risk to patients of a falsely low test result obtained by the LeadCare Ultra Test System. The 'LeadCare Ultra Risk Analysis,' Rev 10 does not list false negative or erroneous result as a potential hazard."

d. "Your firm failed to adequately evaluate the risk of LeadCare II for falsely low results. The 'LeadCare II Risk Analysis,' Rev 6 dated 9/8/2005 identifies a false negative result as a 'Marginal' severity defined as causing 'minor injury, temporary impairment, reversible, minor intervention required' and 'Occasional' probability of 'Likely to occur sometimes'."

73. Even after FDA determined that MAGELLAN was aware of the Malfunction in or around September 2013, Winslow continued to provide the materially false and misleading information that MAGELLAN first discovered the Malfunction in 2014 after receiving complaints from LeadCare Ultra customers. On or about July 11, 2017, Winslow and Employee E met with U.S. congressional staff members in response to a June 12, 2017, letter written by 12 U.S. Senators to FDA and CDC expressing concern about public health issues in light of the

recall of LeadCare Devices. Winslow falsely told congressional staff members that MAGELLAN first became aware of the Malfunction in 2014, and she did not disclose that MAGELLAN had been untruthful and misleading to FDA about material issues related to the Malfunction.

74. On or about December 21, 2017, MAGELLAN sent a letter to an international charitable organization ("Aid Organization A") that provided humanitarian medical care, including lead testing for children whose lead levels put them at risk of permanent brain damage and death. The letter addressed Aid Organization A's "concerns [about] how MAGELLAN handled its corrective actions associated with venous blood testing, including the failure to notify your organization directly of the labeling changes that ultimately resulted in the May 17, 2017 Field Safety Notice issued by the US Food and Drug Administration."

75. The letter to Aid Organization A contained materially false and misleading statements, and concealed material facts, about the Malfunction and MAGELLAN's discovery of the Malfunction. For instance, the letter stated:

> In the Summer/Fall of 2014, MAGELLAN became aware of customer complaints related to suppressed low test results for some venous samples with the LeadCare Ultra System. Suppression of test results was unexpected based on prior clinical trials, was not observed with capillary bloods, and suppression did not appear to be related to lot-specific reagent issues.

This statement was materially false and misleading because suppression of test results was not unexpected and was observed as early as in or around June 2013, before FDA clearance and release of the LeadCare Ultra devices.

76. In or around September 2017, CDC recommended retesting all children under age 6 who had been tested on a LeadCare Ultra, LeadCare II, or LeadCare Plus device using venous samples. However, many states agencies did not track which blood lead samples were tested

using LeadCare Devices. In one state that did identify the patients who were tested using venous samples on LeadCare Devices, the retesting rate was exceedingly low: only 18% of qualified patients were retested. CDC and FDA estimated that the Malfunction caused tens of thousands of children and adults to receive false blood lead results.

ACTION TAKEN IN WRITING BY THE BOARD OF DIRECTORS OF MAGELLAN DIAGNOSTICS, INC.

The undersigned, being all of the members of the Board of Directors (the "**Board**") of Magellan Diagnostics, Inc., a Delaware corporation (the "**Company**"), in accordance with Section 141(f) of the General Corporation Law of Delaware, hereby adopt the following resolutions by unanimous written consent in lieu of a meeting, effective as of May 14, 2024 (the "**Effective Date**"):

WHEREAS, The "Company" has been engaged in discussions with the Office of the United States Attorney for the District of Massachusetts (the "Office") regarding issues arising in relation to violations of federal law concerning the LeadCare II, LeadCare Ultra, and LeadCare Plus devices; and

WHEREAS, in order to resolve such discussions, it is proposed that the Company enter into certain agreements with the Office; and

WHEREAS, the Company's Senior Vice President and General Counsel, Emerson Moser, together with outside counsel for the Company, have advised the Board of Directors of the Company of its rights, possible defenses, the Sentencing Guidelines' provisions, and the consequences of entering into such agreement with the Office;

Therefore, the Board of Directors has RESOLVED that:

1. The Company (a) acknowledges the filing of the two-count Information charging the Company with (1) conspiracy to commit wire fraud in violation of Title 18, United States Code, Sections 1349; and (2) conspiracy to defraud the United States in violation of Title 18, United States Code, Section 371; (b) waives any right it might have to indictment on such charges and enters into a Deferred Prosecution Agreement (the "Agreement") with the Office; and (c) agrees to pay victim compensation as described in the Agreement and its attachments;

2. The Company accepts the terms and conditions of this Agreement, including, but not limited to, (a) a knowing waiver of its rights to a speedy trial pursuant to the Sixth Amendment to the United States Constitution, Title 18, United States Code, Section 3161, and Federal Rule of Criminal Procedure 48(b); and (b) a knowing waiver for purposes of this Agreement and any charges by the United States arising out of the conduct described in the Statement of Facts of any objection with respect to venue and consents to the filing of the Information, as provided under the terms of this Agreement, in the United States District Court for the District of Massachusetts; and (c) a knowing waiver of any defenses based on the statute of limitations for any prosecution relating to the conduct described in the Statement of Facts or relating to conduct known to the Office prior to the Effective Date of this Agreement that is not time-barred by the applicable statute of limitations on the Effective Date of this Agreement;

3. Any President, Executive Vice President or Senior Vice President of the Company, including Mr. Tony Serafini-Lamanna, Mr. Andrew S. Kitzmiller and/or Mr. Emerson C. Moser, is hereby authorized, empowered, and directed, on behalf of the Company, to execute the Deferred

Prosecution Agreement substantially in such form as reviewed by this Board of Directors at this meeting with such changes as the Senior Vice President and General Counsel of the Company, Emerson C. Moser, may approve;

4. The Senior Vice President and General Counsel of the Company, Emerson C. Moser, is hereby authorized, empowered, and directed to take any and all actions as may be necessary or appropriate and to approve the forms, terms, or provisions of any agreement or other documents as may be necessary or appropriate, to carry out and effectuate the purpose and intent of the foregoing resolutions; and

5. All of the actions of the Senior Vice President and General Counsel of the Company, Emerson C. Moser, which actions would have been authorized by the foregoing resolutions except that such actions were taken prior to the adoption of such resolutions, are hereby severally ratified, confirmed, approved, and adopted as actions on behalf of the Company.

Date: May 14, 2024

By:

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Mr. Tony Serafini-Lamanna, Director

DocuSigned by:
Andrew S. Kitzmiller
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Mr. Andrew S. Kitzmiller, Director

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Emerson C. Moser
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Mr. Emerson C. Moser, Director

ATTACHMENT C

CORPORATE COMPLIANCE PROGRAM

In order to address any deficiencies in its internal controls, compliance code, policies, and procedures regarding compliance with the Federal Food, Drug, and Cosmetic Act ("FDCA") and its associated regulations, Magellan Diagnostics, Inc. (the "Company"), on behalf of itself, its parent, and its subsidiaries, agrees to continue to conduct, in a manner consistent with all of its obligations under this Agreement, appropriate reviews of its existing internal controls, compliance code, policies, and procedures.

Where necessary and appropriate, the Company agrees to adopt a new or to modify its existing compliance program, including internal controls, compliance code, policies, and procedures, to ensure that it maintains an effective compliance program that is designed, implemented, and enforced to effectively deter and detect violations of the FDCA and its associated regulations. At a minimum, this should include, but not be limited to, the following elements to the extent they are not already part of the Company's existing internal controls, compliance code, policies, and procedures:

Commitment to Compliance

1. The Company will ensure that its directors and senior management provide strong, explicit, and visible support and commitment to its corporate policy against violations of the FDCA and its associated regulations and the Company's compliance codes and demonstrate rigorous adherence by example. The Company will also ensure that all managers, in turn, reinforce those standards and encourage employees to abide by them. The Company will create and foster a culture of ethics and compliance with the law in its day-to-day operations at all levels of the company.

Policies and Procedures

2. The Company will develop and promulgate a clearly articulated and visible corporate policy requiring adherence to the FDCA and its associated regulations, which policy shall be memorialized in a written compliance code or codes.

3. The Company will take appropriate measures to encourage and support the observance of ethics and compliance policies and procedures by personnel at all levels of the Company. These policies and procedures shall apply to all directors, officers, and employees and, where necessary and appropriate, outside parties acting on behalf of the Company, including, but not limited to, agents and intermediaries, consultants, representatives, distributors, teaming partners, contractors and suppliers, consortia, and joint venture partners (collectively, "agents and business partners"). The Company shall notify all employees that compliance with the policies and procedures is the duty of individuals at all levels of the Company.

4. The Company will ensure that it has a system of procedures, including a system of internal controls, reasonably designed to ensure the maintenance of (1) good manufacturing practices, (2) complaint handling, and (3) the additional quality assurance and regulatory affairs procedures instituted to date by the Company's parent, Meridian Bioscience Inc. This system shall be designed to provide reasonable assurances that, at a minimum:

a. All customer complaints are promptly evaluated for reportability under the FDCA and its associated regulations;

b. Instructions for use and any communications with the Company's customers that modify, amend, or otherwise revise instructions for use are promptly evaluated for compliance with the FDCA and its associated regulations; and

c. All Magellan studies or experiments showing inaccurate test results with any of the Company's products are promptly brought to the attention of senior compliance executives and the Monitor (see Attachment D).

Periodic Risk-Based Review

5. The Company shall review its compliance policies and procedures regarding the FDCA and its associated regulations no less than annually and update them as appropriate to ensure their continued effectiveness, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company and its products.

Proper Oversight and Independence

6. The Company will assign responsibility to one or more senior corporate executives of the Company for the implementation and oversight of the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations. Such corporate official(s) shall have the authority to report directly to independent monitoring bodies, including the Company's Board of Directors, or any appropriate committee of the Board of Directors, and shall have an adequate level of stature and autonomy from management as well as sufficient resources and authority to maintain such autonomy.

Training and Guidance

7. The Company will implement mechanisms designed to ensure that its compliance code, policies, and procedures regarding the FDCA and its associated regulations are effectively communicated to all directors, officers, employees, and, where necessary and appropriate, agents and business partners. These mechanisms shall include: (a) periodic training for all directors and officers, all employees in positions of leadership or trust or in positions that require such training (e.g., regulatory, quality, manufacturing, research and development, sales, marketing, legal,

compliance), and, where necessary and appropriate, agents and business partners; and (b) corresponding certifications by all such directors, officers, employees, agents, and business partners, certifying compliance with the training requirements. The Company will conduct training in a manner tailored to the audience's size, sophistication, or subject matter expertise and, where appropriate, will discuss prior compliance incidents.

8. The Company will maintain, or where necessary establish, an effective system for providing guidance and advice to directors, officers, employees, and, where necessary and appropriate, agents and business partners, on complying with the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations, including when they need advice on an urgent basis.

Internal Reporting and Investigation

9. The Company will maintain, or where necessary establish, an effective system for internal and, where possible, confidential reporting by, and protection of, directors, officers, employees, and, where appropriate, agents and business partners concerning violations of the FDCA and its associated regulations or the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations.

10. The Company will maintain, or where necessary establish, an effective and reliable process with sufficient resources for responding to, investigating, and documenting allegations of violations of the FDCA and its associated regulations or the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations. The Company will handle the investigations of such complaints in an effective manner, including routing the complaints to proper personnel, conducting timely and thorough investigations, and following up with appropriate discipline where necessary.

Enforcement and Discipline

11. The Company will implement mechanisms designed to effectively enforce its compliance code, policies, and procedures, including appropriately incentivizing compliance and disciplining violations. At a minimum, these mechanisms will include policies that incorporate adherence to compliance as one portion of employee and officer evaluations, that impose financial penalties for compliance-related misconduct, and that provide affirmative incentives for compliance-promoting behavior.

12. The Company will institute appropriate disciplinary procedures to address, among other things, violations of the FDCA and its associated regulations and the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations by the Company's directors, officers, and employees. Such procedures should be applied consistently, fairly, and in a manner commensurate with the violation, regardless of the position held by, or perceived importance of, the director, officer, or employee. The Company shall implement procedures to ensure that where misconduct is discovered, reasonable steps are taken to remedy the harm resulting from such misconduct, and to ensure that appropriate steps are taken to prevent further similar misconduct, including assessing the internal controls, compliance code, policies, and procedures and making modifications necessary to ensure the overall compliance program is effective.

Mergers and Acquisitions

13. The Company will develop and implement policies and procedures for mergers and acquisitions requiring that the Company conduct appropriate risk-based due diligence on potential new business entities, including appropriate due diligence regarding the FDCA and its associated regulations by legal and compliance personnel.

14. The Company will ensure that the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations apply as quickly as is practicable to newly acquired businesses or entities merged with the Company and will promptly:

a. train the directors, officers, employees, consultants, agents, and business partners consistent with Paragraph 8 above on the FDCA and its associated regulations and the Company's compliance code, policies, and procedures regarding the FDCA and its associated regulations; and

b. conduct an audit of all newly acquired or merged businesses as quickly as practicable concerning compliance with the FDCA and its associated regulations.

Monitoring, Testing, and Remediation

15. In order to ensure that its compliance program does not become stale, the Company will conduct periodic reviews and testing of its compliance codes, policies, and procedures regarding the FDCA and its associated regulations designed to evaluate and improve their effectiveness in preventing and detecting violations of the FDCA and its associated regulations and the Company's compliance codes, policies, and procedures regarding the FDCA and its associated regulations, taking into account relevant developments in the field, evolving industry standards, and the risk profile of the Company and its products. The Company will ensure that compliance and control personnel have sufficient direct or indirect access to relevant sources of data to allow for timely and effective monitoring and/or testing. Based on such review and testing and its analysis of any prior misconduct, the Company will conduct a thoughtful root cause analysis and timely and appropriately remediate to address the root causes.

ATTACHMENT D

COMPLIANCE REPORTING REQUIREMENTS

The duties and authority of the Independent Compliance Monitor (the "Monitor"), and the obligations of Magellan Diagnostics, Inc. ("Magellan" or the "Company"), on behalf of itself, its parent, and its subsidiaries, with respect to the Monitor and the United States Attorney's Office for the District of Massachusetts (the "Office") are as described below. In addition, the Company agrees that it will report to the Office periodically. The Monitor and Company shall transmit copies of all work plans, reports, certifications, and other notices to the Office as required herein in accordance with the requirements for all notices as described in the Deferred Prosecution Agreement (the "Agreement").

Independent Compliance Monitor

1. The Company will retain the Monitor for a period of 24 months (the "Term of the Monitorship"), unless the Office terminates the Agreement early or extends it as provided for in Paragraph 3 of the Agreement. Notwithstanding the foregoing, the Company agrees that the Monitor's role as claims administrator shall continue for a 36-month period as set forth in Attachment F.

Monitor's Mandate

2. The Monitor's primary responsibility is to assess and monitor the Company's compliance with the terms of the Agreement, including the Corporate Compliance Program in Attachment C, to ensure the Company is promoting and executing on a culture in which the compliance function is given adequate resources and compliance concerns are given due attention from management at all levels. During the Term of the Monitorship, the Monitor will evaluate, in the manner set forth below, the effectiveness of the policies and procedures, internal controls,

training, and record-keeping as they relate to the Company's current and ongoing compliance with the FDCA and its associated regulations and take such reasonable steps as, in the Monitor's view, may be necessary to fulfill the foregoing mandate (the "Mandate"). This Mandate shall include an assessment of the Board of Directors' and senior management's commitment to, and effective implementation of, the Corporate Compliance Program described in Attachment C. In addition, this Mandate shall include (i) overseeing the Company's efforts to identify and notify potential victims; (ii) reviewing and evaluating victim compensation claims; and (iii) overseeing the Company's payment of victim compensation claims according to the processes and standards further described in Attachment F.

Company's Obligations

3. The Company shall cooperate fully with the Monitor, and the Monitor shall have the authority to take such reasonable steps as, in the Monitor's view, may be necessary to be fully informed about the Company's compliance program in accordance with the principles set forth herein and subject to applicable law, including any applicable data protection and labor laws and regulations. To that end, the Company shall: facilitate the Monitor's access to the Company's documents and resources; not limit such access, except as provided in Paragraphs 5–6; and, where necessary, provide guidance on applicable local law (such as relevant data protection and labor laws). The Company shall provide the Monitor with access to all information, documents, records, facilities, and employees, as reasonably requested by the Monitor, that fall within the scope of the Mandate of the Monitor under the Agreement. The Company shall use its best efforts to provide the Monitor with access to the Company's former employees and its third-party vendors, agents, and consultants.

4. Any disclosure by the Company to the Monitor concerning violations of the FDCA and its associated regulations shall not relieve the Company of any otherwise applicable obligation to truthfully disclose such matters to the Office as described below under the heading, "Additional Reporting Requirements."

Withholding Access

5. The parties agree that no attorney-client relationship shall be formed between the Company and the Monitor. In the event that the Company seeks to withhold from the Monitor access to information, documents, records, facilities, or current or former employees of the Company that may be subject to a claim of attorney-client privilege or to the attorney work-product doctrine, or where the Company reasonably believes production would otherwise be inconsistent with applicable law, the Company shall work cooperatively with the Monitor to resolve the matter to the satisfaction of the Monitor.

6. If the matter cannot be resolved, at the request of the Monitor, the Company shall promptly provide written notice to the Monitor and the Office. Such notice shall include a general description of the nature of the information, documents, records, facilities, or current or former employees that are being withheld, as well as the legal basis for withholding access. The Office may then consider whether to make a further request for access to such information, documents, records, facilities, or employees.

Monitor's Coordination with the Company and Review Methodology

7. In carrying out the Mandate, to the extent appropriate under the circumstances, the Monitor should coordinate with Company personnel, including in-house counsel, compliance personnel, regulatory and quality personnel, manufacturing personnel, and internal auditors, on an ongoing basis. The Monitor may rely on the product of the Company's existing processes (e.g.,

the results of studies, reviews, sampling and testing methodologies, audits, and analyses conducted by or on behalf of the Company), as well as the Company's internal resources (e.g., legal, compliance, regulatory, quality, and internal audit), which can assist the Monitor in carrying out the Mandate through increased efficiency and Company-specific expertise, provided that the Monitor has confidence in the quality of those resources.

8. The Monitor's reviews should use a risk-based approach, and thus, the Monitor is not expected to conduct a comprehensive review of all business activities. In carrying out the Mandate, the Monitor should consider, for instance, risks presented by: (a) the blood lead-testing industry; (b) the Company's products; (c) the Company's customers; (d) the Company's current and future business opportunities and transactions; and (e) current and potential business partners, including third parties and joint ventures.

9. In undertaking the reviews to carry out the Mandate, the Monitor shall formulate conclusions based on, among other things: (a) inspection of relevant documents, including the Company's current compliance policies and procedures regarding the FDCA and its associated regulations; (b) on-site observation of selected systems and procedures of the Company, including those related to internal controls, record-keeping, quality, regulatory, and internal audits; (c) meetings with, and interviews of, relevant current and, where appropriate, former directors, officers, employees, business partners, agents, and other persons at mutually convenient times and places; and (d) analyses, studies, and testing of the Company's compliance program.

Monitor's Written Work Plans

10. To carry out the Mandate, during the Term of the Monitorship, the Monitor shall conduct an initial ("first") review and submit a first report, followed by follow-up review(s) and report(s) as described in Paragraphs 16–19 below. With respect to the first report, after consultation

with the Company and the Office, the Monitor shall prepare and submit the first written work plan within 30 calendar days of being retained, and the Company and the Office shall provide any comments within 30 calendar days after receipt of the written work plan. With respect to a follow-up report, after consultation with the Company and the Office, the Monitor shall prepare and submit a written work plan at least 30 calendar days prior to commencing a review, and the Company and the Office shall provide any comments within 20 calendar days after receipt of the written work plan. Any disputes between the Company and the Monitor with respect to any written work plan shall be decided by the Office in its sole discretion.

11. All written work plans shall identify with reasonable specificity the activities the Monitor plans to undertake in execution of the Mandate, including a written request for documents. The Monitor's work plan for the first review shall include such steps as are reasonably necessary to conduct an effective first review in accordance with the Mandate, including by developing an understanding, to the extent the Monitor deems appropriate, of the facts and circumstances surrounding any violations that may have occurred before the date of the Agreement. In developing such understanding, the Monitor is to rely, to the extent possible, on available information and documents provided by the Company. It is not intended that the Monitor will conduct the Monitor's own inquiry into the historical events that gave rise to the Agreement.

First Review

12. The first review shall commence no later than 60 calendar days from the date of the retention of the Monitor (unless otherwise agreed by the Company, the Monitor, and the Office). The Monitor shall prepare and submit to the Board of Directors of the Company and the Office a written report within 90 calendar days of commencing the first review, setting forth the Monitor's assessment and, if necessary, making recommendations reasonably designed to improve the

effectiveness of the Company's program for ensuring compliance with the FDCA and its associated regulations. The Monitor should consult with the Company concerning his or her findings and recommendations on an ongoing basis and should consider the Company's comments and input to the extent the Monitor deems appropriate. The Monitor may also choose to share a draft of the Monitor's report with the Company prior to finalizing it. The Monitor's report need not recite or describe comprehensively the Company's history or compliance policies, procedures and practices. Rather, the report should focus on areas the Monitor has identified as requiring recommendations for improvement or which the Monitor otherwise concludes merit particular attention. After consultation with the Company and with prior written approval of the Office, the Monitor may extend the period for submission of the first report for a brief time.

13. Within 90 calendar days after receiving the Monitor's first report, the Company shall adopt and implement all recommendations in the report unless, within 45 calendar days after receiving the report, the Company notifies the Monitor and the Office in writing concerning any recommendations that the Company considers unduly burdensome, inconsistent with applicable law or regulation, impractical, excessively expensive, or otherwise inadvisable. With respect to any such recommendation, the Company shall include in its written notice a proposal for an alternative policy, procedure, or system designed to achieve the same objective or purpose, and the Company need not adopt that recommendation within the 90 calendar days of receiving the report. As to any recommendation on which the Company and the Monitor do not agree, such parties shall attempt in good faith to reach an agreement within 30 calendar days after the Company serves the written notice.

14. In the event the Company and the Monitor are unable to agree on an acceptable alternative proposal, the Company shall promptly consult with the Office. The Office may consider

the Monitor's recommendation and the Company's reasons for not adopting the recommendation in determining whether the Company has fully complied with its obligations under the Agreement. Pending such determination, the Company shall not be required to implement any contested recommendation(s).

15. With respect to any recommendation that the Monitor determines cannot reasonably be implemented within 150 calendar days after receiving the report, with prior written approval of the Office, the Monitor may extend the period for implementation.

Follow-Up Review(s)

16. A follow-up review shall commence no later than 180 calendar days after the submission of the first report (unless otherwise agreed by the Company, the Monitor, and the Office). The Monitor shall prepare and submit to the Board of Directors of the Company and the Office a written follow-up ("second") report within 120 calendar days of commencing the second review, setting forth the Monitor's assessment and, if necessary, making recommendations in the same fashion as set forth in Paragraph 12 with respect to the first review. After consultation with the Company and with prior written approval of the Office, the Monitor may extend the period for submission of the second report for a brief time.

17. Within 120 calendar days after receiving the Monitor's second report, the Company shall adopt and implement all recommendations in the report, unless, within 30 calendar days after receiving the report, the Company notifies the Monitor and the Office in writing concerning any recommendations that the Company considers unduly burdensome, inconsistent with applicable law or regulation, impractical, excessively expensive, or otherwise inadvisable. With respect to any such recommendation, the Company shall include in its written notice a proposal for an alternative policy, procedure, or system designed to achieve the same objective or purpose, and

the Company need not adopt that recommendation within the 120 calendar days of receiving the report. As to any recommendation on which the Company and the Monitor do not agree, such parties shall attempt in good faith to reach an agreement within 30 calendar days after the Company serves the written notice.

18. In the event the Company and the Monitor are unable to agree on an acceptable alternative proposal, the Company shall promptly consult with the Office. The Office may consider the Monitor's recommendation and the Company's reasons for not adopting the recommendation in determining whether the Company has fully complied with its obligations under the Agreement. Pending such determination, the Company shall not be required to implement any contested recommendation(s). With respect to any recommendation that the Monitor determines cannot reasonably be implemented within 120 calendar days after receiving the report, with prior written approval of the Office, the Monitor may extend the period for implementation.

19. In the event that the Office extends the term of the Monitorship as provided for in Paragraph 3 of the Agreement, the Monitor shall undertake a second follow-up ("third") review not later than 150 calendar days after the submission of the second report. The Monitor shall prepare and submit to the Board of Directors of the Company and the Office a third report within 120 calendar days of commencing the review, and recommendations shall follow the same procedures described in Paragraphs 16–18. No later than 30 calendar days before the end of the Term of the Monitorship, the Monitor also shall submit to the Office a certification as to whether the Company's compliance program, including its policies, procedures, and internal controls, is reasonably designed and implemented to prevent and detect violations of the FDCA and its associated regulations.

Monitor's Discovery of Reportable Events

20. Except as set forth below in Paragraph 21, should the Monitor discover circumstances during the course of his or her engagement that, after a reasonable opportunity to conduct an appropriate review or investigation of the allegations, a reasonable person would consider a material violation of the FDCA and its associated regulations (a "Reportable Event"), the Monitor shall immediately report the Reportable Event to the Company's or the Company's parent's General Counsel and/or Chief Compliance Officer for further action, unless the Reportable Event was already so disclosed. The Monitor also may report the Reportable Event to the Office at any time and shall report the Reportable Event to the Office when it requests the information.

21. If the Monitor believes that a Reportable Event poses a substantial risk of harm to the public or may constitute a felony under U.S. federal law, the Monitor shall immediately report such solely to the Office, and in such cases, disclosure of the same to the General Counsel or Chief Compliance Officer of the Company or the Company's parent should occur as the Office deems appropriate under the circumstances.

22. The Monitor shall address in his or her reports the appropriateness of the Company's response to disclosed Reportable Events whether previously disclosed to the Office or not. Further, if the Company or any entity or person working directly or indirectly on behalf of the Company withholds information necessary for the performance of the Monitor's responsibilities and the Monitor believes that such withholding is without just cause, the Monitor shall also immediately disclose that fact to the Office and address the Company's failure to disclose the necessary information in his or her reports.

23. Neither the Company nor anyone acting on its behalf shall take any action to retaliate against the Monitor for any such disclosures or for any other reason.

Additional Reporting Requirements

24. The Company shall submit written reports to the Office concerning Reportable Events on a biannual basis, whether previously disclosed to the Office by the Monitor or not. A Reportable Event may be the result of an isolated event or a series of occurrences. The written report shall include: (a) whether any Reportable Events have been determined to have occurred during the preceding calendar quarter, and providing updated information about Reportable Events that the Company determined to have occurred during any prior calendar quarter, as may be necessary in the reasonable determination of the Company or at the Office's request; (b) a description of the Reportable Event, including the relevant facts, the positions of the persons involved, and the legal authorities implicated; (c) a description of the Company's actions taken to investigate and correct the Reportable Event; and (d) a description of any further steps the Company plans to take to address the Reportable Event and prevent it from recurring. The written reports shall be submitted to the Office no later than 15 calendar days after the end of each calendar semester (that is, by January 15 for the calendar semester ending December 31, and July 15 for the calendar semester ending June 30), excepting any calendar semester that ends within 30 calendar days of the expiration of the Agreement.

25. No later than 12 months from the Effective Date of this Agreement, the Company shall submit to the Office a certification from the Chief Executive Officer of the Company, in the form of executing the document attached as Attachment E to this Agreement. The certification will be deemed a material statement and representation by the Company to the executive branch of the United States for purposes of 18 U.S.C. §§ 1001 and 1519, and it will be deemed to have been

made in the District of Massachusetts. The Company shall deliver a second certification no later than 12 months after the first certification, and if the Office extends the term of the Monitorship as provided for in Paragraph 3 of the Agreement, a final certification no later than 30 calendar days before the expiration of the Agreement.

Additional Information and Meetings During the Agreement

26. Upon request of the Office in its sole discretion, the Company shall provide to the Office additional information or documents regarding its compliance-related improvements, processes, and controls, or regarding its victim identification and compensation efforts as described in Attachment F. The Company's cooperation pursuant to this Paragraph is subject to applicable law and regulations, as well as valid claims of attorney-client privilege or attorney work product doctrine; however, the Company must provide to the Office a log of any information or cooperation that is not provided based on an assertion of law, regulation, or privilege, and the Company bears the burden of establishing the validity of any such an assertion.

27. If and when the Office deems it appropriate in its sole discretion, representatives from the Company, the Monitor, and the Office will meet to discuss the status of the review and reporting obligations, and any suggestions, comments, or improvements the Company or Monitor may wish to discuss with or propose to the Office.

Confidentiality of Submissions

28. Submissions by the Monitor and the Company, including the work plans and reports, will likely include proprietary, financial, confidential, and competitive business information. Moreover, public disclosure of the submissions could discourage cooperation, impede pending or potential government investigations, and thus undermine the objectives of the monitorship and reporting requirements. For these reasons, among others, the submissions and the

contents thereof are intended to remain and shall remain non-public and exempt from disclosure pursuant to a Freedom of Information Act (FOIA) request, except as otherwise agreed to by the parties in writing, or except to the extent the Office determines in its sole discretion that disclosure would be in furtherance of the Office's discharge of its duties and responsibilities or is otherwise required by law.

ATTACHMENT E

CERTIFICATION

To: United States Attorney's Office for the District of Massachusetts
One Courthouse Way, Suite 9200, Boston, MA 02210
Attention: Health Care Fraud Chief

Re: Magellan Diagnostics, Inc. Deferred Prosecution Agreement Disclosure Certification

The undersigned certifies, pursuant to Attachment D of the Deferred Prosecution Agreement ("DPA") filed on May 21, 2024 in the U.S. District Court for the District of Massachusetts, by and between the United States Attorney's Office for the District of Massachusetts (the "Office") and Magellan Diagnostics, Inc. (the "Company"), that the undersigned is aware of the Company's obligations under Attachment D of the DPA and has reviewed the Monitor's written work plans and compliance reports to date. The undersigned further certifies that to date, the Company has disclosed to the Office all Reportable Events as required by Attachment D of the DPA.

The undersigned further acknowledges and agrees that the reporting requirements contained in Attachment D of the DPA and the representations contained in this certification constitute a significant and important component of the DPA and the Office's determination of whether the Company has satisfied its obligations under the DPA.

The undersigned hereby certifies that he is the Senior Vice President and General Counsel of the Company and has been duly authorized by the Company to sign this Certification on behalf of the Company.

This Certification shall constitute a material statement and representation by the undersigned and by, on behalf of, and for the benefit of, the Company to the executive branch of the United States for purposes of 18 U.S.C. §1001, and such material statement and representation shall be deemed to have been made in the District of Massachusetts. This Certification shall also constitute a record, document, or tangible object in connection with a matter within the jurisdiction of a department and agency of the United States for purposes of 18 U.S.C. §1519, and such record, document, or tangible object shall be deemed to have been made in the District of Massachusetts.

By: ______________________ Dated: 5/21/24

EMERSON C. MOSER
SVP, General Counsel
Magellan Diagnostics, Inc.

ATTACHMENT F

VICTIM COMPENSATION PROGRAM

The duties and authority of the Independent Compliance Monitor (the "Monitor"), and the obligations of Magellan Diagnostics, Inc. ("Magellan" or "the Company") with respect to victim outreach, identification, and compensation are as described below. These processes and procedures shall govern the funding and administration of the Victim Compensation Fund, and such additional payments as may be required, as described in Paragraphs 6 through 9 of the Deferred Prosecution Agreement ("Agreement") with the United States Attorney's Office for the District of Massachusetts (the "Office").

General Principles

1. The Company agrees to pay victim compensation in connection with the Agreement and in lieu of court-ordered restitution in connection with its guilty plea to the FDCA Information (as defined in the Agreement).

Company's Payment Obligations

2. The Company agrees to establish a Victim Compensation Fund of at least $9,300,000 to compensate patients and/or minor patients' legal guardians who were harmed by the conduct described in the Statement of Facts between June 27, 2013 and May 31, 2017. The Company shall establish a dedicated bank account for the Victim Compensation Fund and make deposits to the account according to the following schedule: $3,000,000 shall be deposited no later than 15 days after the Effective Date of this Agreement; $3,000,000 shall be deposited no later than one year after the Effective Date of this Agreement; and $3,300,000 shall be deposited no later than two years after the Effective Date of this Agreement.

3. The Monitor shall evaluate victim compensation claims and shall make recommendations to the Office regarding the individuals who should receive payments from the Victim Compensation Fund and the compensation amounts that these individuals should receive. Only the Office shall be empowered to make final decisions regarding who should receive payments from the Victim Compensation Fund and the compensation amounts that these individuals should receive.

4. Should the Monitor recommend and the Office approve payment in excess of the amount in the dedicated bank account, the Company shall deposit additional funds into the dedicated bank account within 90 days of such determination in order to permit those claims to be paid.

5. The Company agrees to pay all costs, fees, and expenses incurred by the Monitor in connection with the claims administration process and any fees associated with the dedicated bank account. The Company may, with approval of the Monitor, use funds in the dedicated bank account to pay for reasonable costs associated with its notification obligations below, provided that any funds expended shall not diminish the Company's obligations pursuant to Paragraph 4.

Company's Victim Notification and Identification Obligations

6. Within 30 days of the Effective Date of the Agreement, the Company shall make a public notice on its website in a suitably prominent location, describing the Company's resolution with the Office and the availability of compensation for victims. The website shall include contact information for patients to seek additional information or to submit a claim. The Company shall coordinate with the Monitor on the manner of receiving and organizing claims or requests for information.

7. In addition, the Company will promptly initiate a patient identification program to affirmatively identify individuals who may have been harmed by the conduct described in the Statement of Facts. That program will include the following minimum elements:

a. The Company shall retain at least one fulltime employee ("FTE") whose responsibility will be to identify patients who may have been harmed by the conduct described in the Statement of Facts. The Company shall retain the FTE in this role for at least 24 months.

b. The FTE will review and analyze data and records of patients identified by the Office including but not limited to patients who (a) received venous blood lead test results from a LeadCare II, LeadCare Ultra, or LeadCare Plus device or (b) responded to FBI's victim identification survey in *United States v. Amy Winslow et al.*, Case No. 23-cr-10094-PBS.

c. The FTE will review and analyze information from the Company, including but not limited to customer complaints to identify patients who may have been harmed by the conduct described in the Statement of Facts.

d. The FTE will work directly with the Company's customers from the relevant period (*i.e.*, doctors, clinics, hospitals) and the 62 state and local Childhood Lead Poisoning Prevention Programs ("CLPPPs") to identify and contact potentially harmed individuals. If the Company customer or the CLPPP is not willing or able to identify the patients because of time or resource limitations, the Company will provide financial reimbursement and/or other assistance for patient identification purposes.

e. The Company will structure the FTE's compensation to incentivize timely completion of milestones designed, in consultation with the Monitor, to result in the

successful identification of patients who may have been harmed by the conduct described in the Statement of Facts.

f. The Company shall notify any patient who may have been harmed by the conduct described in the Statement of Facts and identified as a result of this program of the availability for victim compensation and the process for submitting claims. The Company shall also provide such patients with information about other forms of assistance or services that may be helpful under their individual circumstances.

8. The Company shall promptly and fully inform the Monitor of the steps the Company takes pursuant to Paragraphs 6–7. The Company shall implement the Monitor's reasonable recommendations concerning any modifications to the Company's notice and patient identification program designed to efficiently and effectively identify and notify patients who may have been harmed. Should the Company and the Monitor disagree as to any such recommendation, such parties shall attempt in good faith to reach an agreement within 30 days. In the event that the Company and the Monitor remain unable to agree as to such a recommendation at the conclusion of thirty days, the Company shall promptly consult with the Office. The Office may consider the Monitor's recommendation and the Company's reasons for not adopting the recommendation in determining whether the Company has fully complied with its obligations under the Agreement.

9. The Monitor shall provide quarterly updates to the Office regarding the status of the patient identification program.

Monitor's Role as Claims Administrator

10. The Monitor shall act as a claims administrator for the Victim Compensation Fund. In conjunction with the Company and the expert retained pursuant to Paragraph 13, the Monitor shall propose a compensation system—subject to approval by the Office—for patients who were

harmed by the conduct described in the Statement of Facts. The Monitor's proposed compensation system shall include all demonstrated pecuniary damages for harm suffered by patients or their legal guardian(s) as a result of delayed detection of lead poisoning or lead exposure.

11. The Monitor's proposed compensation system shall not include any non-pecuniary damages for harm suffered by patients or their legal guardian(s) as a result of delayed detection of lead poisoning or lead exposure.

12. The Monitor's proposed compensation system shall not include any purported attorney fees or other related legal costs incurred by any victim, and such fees/costs shall not be compensable from the Fund.

13. The Monitor shall retain a qualified expert on lead issues as a consultant to evaluate patient circumstances and compensation amounts to assist in evaluating claims.

14. Any individual (or individual's legal guardian) who believes he or she is entitled to compensation must submit a claim to the Monitor within two years of the Monitor being selected (the "Claims Period"). Only one claim may be submitted on behalf of a patient by the patient or any of his or her legal guardian(s).

15. The Monitor shall make recommendations to the Office regarding individuals who should receive payments from the Victim Compensation Fund and the compensation amounts that these individuals should receive. The Monitor shall make its recommendations to the Office within 90 days of the conclusion of the Claims Period and shall identify any pending claims that the Monitor has not yet resolved. The Office shall review the Monitor's recommendations and shall make final determinations of disbursements from the Victim Compensation Fund within 90 days of receiving the Monitor's recommendations. The Office shall notify the Company and the Monitor of its final determinations. The Company shall then have 90 days to make disbursements

to victims from the dedicated bank account (the "Victim Payment Period") or, to the extent the Company reasonably believes that a determination by the Office is inconsistent with the terms of the DPA or the compensation framework contemplated by Paragraph 10, seek review by the Judge to whom the matter is assigned.

16. Any individual who receives compensation under the Victim Compensation Fund shall agree, as a condition of receiving payment from the Victim Compensation Fund, that any future recovery, payment, settlement, or compensation received from the Company for the same harm addressed by the Victim Compensation Fund (e.g., from a Federal or State civil proceeding or other source) shall be reduced by the amount the individual received from the Victim Compensation Fund by executing the acknowledgement included as Attachment F-1.

Disposition of Unused Victim Compensation Funds

17. Any portion of the Victim Compensation Fund that (a) has not been paid out to victims at the conclusion of the Victim Payment Period and (b) is not subject to a pending claim submitted to the Monitor, shall be paid to CLPPPs. Any portion of the Victim Compensation Fund that is subject to a pending claim submitted to the Monitor shall remain in the dedicated bank account until the claim is fully resolved, after which the remaining funds, if any, shall be paid to CLPPPs. Under no circumstances shall any portion of the Victim Compensation Fund revert to the Company or its affiliates.

18. At the conclusion of the Victim Payment Period or resolution of all pending claims, whichever is later, the Monitor shall determine the amount, if any, of unused Victim Compensation Funds to be paid to CLPPPs. The Monitor shall determine—subject to approval by the Office—which CLPPPs are qualified to receive payments and the amount that each CLPPP should receive

from the remaining funds. The Company shall then have 90 days to disburse the remaining funds to CLPPPs as directed by the Monitor.

ATTACHMENT F-1

ACKNOWLEDGMENT & AUTHORIZATION

I, ___________________________, hereby acknowledge that I have read, understand, and agree to the conditions of accepting a payment from the Victim Compensation Fund ("Fund") set forth in Attachment F to the Deferred Prosecution Agreement between Magellan Diagnostics, Inc. ("Magellan") and the United States of America, arising out of Case No. 23-cr-__________ (the "DPA"). I have had the opportunity to consult with an attorney before making this decision, and I voluntarily accept payment from the Fund on these terms.

I HAVE READ THIS ACKNOWLEDGMENT & AUTHORIZATION AND UNDERSTAND THE CONTENTS THEREOF.

Signature:___________________________ Date:_________________________

Print Name:__________________________

On Behalf Of:_________________________
(if applicable)

ATTACHMENT G

ACKNOWLEDGEMENT AND GUARANTY

This Acknowledgement and Guaranty (this "Guaranty") sets forth the terms of the agreement between the United States Attorney's Office for the District of Massachusetts (the "Office") and Meridian Bioscience, Inc. ("Meridian") in connection with the Deferred Prosecution Agreement between the Office and Magellan Diagnostics, Inc. ("Magellan").

Meridian acquired Magellan in March 2016, and Magellan remains a wholly owned subsidiary of Meridian. In exchange for the Office's agreement to enter into the Deferred Prosecution Agreement with Magellan, Meridian agrees as follows:

1. Meridian irrevocably and unconditionally guarantees the performance of all financial obligations agreed to by Magellan in the Deferred Prosecution Agreement and Magellan's plea agreement in connection with the FDCA Information. These financial obligations are:

   a. Magellan's payment of $32,700,000 in criminal fines and forfeiture in connection with the FDCA Information, as set forth in Magellan's plea agreement (the "Criminal Fine and Forfeiture"); *and*

   b. Magellan's payment of victim compensation of at least $9,300,000 as detailed in the Deferred Prosecution Agreement and attachments thereto (the "Victim Compensation Payment").

2. All financial obligations agreed to by Magellan in the Deferred Prosecution Agreement and described in Paragraph 1 of this Guaranty shall be due and payable immediately by Meridian in the event that, during the Term[1] of the Deferred Prosecution Agreement:

[1] "Term" shall have the meaning ascribed in the Deferred Prosecution Agreement.

a. Magellan fails to make a timely payment with respect to the Criminal Fine and Forfeiture and fails to cure such default pursuant to the terms set forth in Magellan's plea agreement concerning the FDCA Information;

b. Magellan fails to timely make the Victim Compensation Payment and fails to cure such default pursuant to the terms of the Deferred Prosecution Agreement; or

c. Magellan or a third party commences an Insolvency Proceeding.[2]

3. The Office shall not be obligated to enforce or exhaust its remedies against Magellan under the Deferred Prosecution Agreement or Magellan's plea agreement concerning the FDCA Information before proceeding to enforce this Guaranty.

4. Meridian acknowledges and agrees to be bound by paragraph 24 of the Deferred Prosecution Agreement. Specifically, except as may otherwise be agreed by the parties in connection with a particular transaction, Meridian agrees that in the event that, during the term of the Deferred Prosecution Agreement, Magellan undertakes any change in corporate form, including if it sells, merges, or transfers business operations that are material to Magellan's operations, or to the operations of any parent company, subsidiaries, or affiliates involved in the conduct described in the Statement of Facts, as they exist as of the Effective Date of the Deferred Prosecution Agreement, whether such sale is structured as a sale, asset sale, merger, transfer, or other change in corporate form, it shall include in any contract for sale, merger, transfer, or other change in corporate form a provision binding the purchaser, or any successor in interest thereto, to the obligations described in the Deferred Prosecution Agreement. The purchaser or successor in

[2] "Insolvency Proceeding" shall have the meaning ascribed in the Deferred Prosecution Agreement.

interest must also agree in writing that the Office's ability to determine a breach under the Deferred Prosecution Agreement is applicable in full force to that entity. Meridian agrees that the failure to include these provisions in the transaction will make any such transaction null and void. Meridian and Magellan shall provide notice to the Office at least 30 business days prior to undertaking any such sale, merger, transfer, or other change in Magellan's corporate form. The Office shall notify Meridian and Magellan prior to such transaction (or series of transactions) if the Office determines that the transaction(s) will have the effect of circumventing or frustrating the enforcement purposes of the Deferred Prosecution Agreement. At any time during the Term that Magellan or Meridian engages in a transaction(s) that has the effect of circumventing or frustrating the enforcement purposes of the Deferred Prosecution Agreement, the Office may deem it a breach of the Deferred Prosecution Agreement pursuant to Paragraph 20 of that agreement. Nothing herein shall restrict Magellan or Meridian from indemnifying (or otherwise holding harmless) the purchaser or successor in interest for penalties or other costs arising from any conduct that may have occurred prior to the date of the transaction, so long as such indemnification does not have the effect of circumventing or frustrating the enforcement purposes of the Agreement, as determined by the Office.

5. Meridian agrees that its obligations under this Guaranty are irrevocable, continuing, absolute, and unconditional and shall not be discharged or impaired or otherwise affected by any illegality, invalidity, or unenforceability of any obligation under this Guaranty. Meridian hereby unconditionally and irrevocably waives any right to revoke this Guaranty and waives any defenses to enforcement of this Guaranty based on the reasons set forth in this paragraph.

6. This Guaranty is governed by the laws of the United States. The exclusive venue for any dispute relating to this Guaranty is the United States District Court for the District of Massachusetts.

7. This Guaranty may be executed in counterparts, each of which constitutes an original and all of which constitute one and the same Agreement.

8. This Guaranty is binding on Meridian's successors, transferees, heirs, and assigns.

9. If any provision of this Guaranty is to any extent determined by final decision of a court of competent jurisdiction to be unenforceable, the remainder of this Guaranty shall not be affected thereby, and each provision of this Guaranty shall be valid and enforceable to the fullest extent permitted by law.

AGREED AND ACCEPTED:

Date: 5/21/24

By: ______________________

EMERSON C. MOSER
As Authorized Corporate Representative for
Meridian Bioscience, Inc.